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HIGH RISK OCCUPATIONAL DISEASE NOTIFICATION AND PREVENTION ACT OF 1987

HEARINGS

BEFORE THE

SUBCOMMITTEE ON LABOR

OF THE

COMMITTEE ON
LABOR AND HUMAN RESOURCES
UNITED STATES SENATE

ONE HUNDREDTH CONGRESS

FIRST SESSION

ON

S. 79

TO NOTIFY WORKERS WHO ARE AT RISK OF OCCUPATIONAL DISEASE IN ORDER TO ESTABLISH A SYSTEM FOR IDENTIFYING AND PREVENTING ILLNESS AND DEATH OF SUCH WORKERS, AND FOR OTHER PURPOSES

MARCH 9, 1987

PART 2

Printed for the use of the Committee on Labor and Human Resources

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HIGH RISK OCCUPATIONAL DISEASE NOTIFICATION AND PREVENTION ACT OF 1987

MONDAY, MARCH 9, 1987

U.S. SENATE,
SUBCOMMITTEE ON LABOR,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, DC.

The subcommittee met, pursuant to notice, at 10 a.m., in room SD-430, Dirksen Senate Office Building, Senator Dan Quayle, presiding

Present: Senators Quayle and Humphrey.

OPENING STATEMENT OF SENATOR QUAYLE

Senator QUAYLE. The Committee will come to order.

The purpose of this hearing is to discuss legislative proposals designed to address the question of notification to individuals who are considered to be at risk of contracting a disease as a result of their exposure to a hazardous substance or physical agent.

A few weeks ago, my distinguished colleague Senator Metzenbaum, Chairman of this Subcommittee, introduced Senate Bill 79, the High-Risk Occupational Disease Notification and Prevention Act of 1987.

On March the 3d, I introduced my own proposal, S. 638, the Health Risk Notification Act of 1987. I developed alternative legislation on this subject because while I believe S. 79 addresses an important problem to which I believe the Congress should respond, I also believe that its solution is very seriously flawed. In my view, its most troublesome flaws relate to its inadequate scientific and medical basis and its virtually unprecedented liability potential.

The issue of worker notification arose about a decade ago in the context of a controversy over whether the National Institute for Occupational Safety and Health ought to provide individual notification to workers found through its retrospective cohort mortality studies to be at increased risk of disease as a result of their exposure to an occupational hazard.

Discussion concerning notification and under what conditions and circumstances it should be done has been ongoing for a number of years and has raised a series of very complex and technical, scientific, medical, ethical and legal questions. I believe that many of these questions are legitimate, but they are questions to which there are no easy and simplistic solutions.

I have tried to craft my proposal in a fashion that addresses these problems equitably and responsibly. If the Congress decides to pass notification legislation—which I think that it will—it is incumbent upon the Congress to be responsible about where, when and how to notify people that they are at risk of contracting a disease.

We should not enact legislation that will in essence put the Federal government in the position of yelling "Fire" in a crowded theater.

Therefore, I have worked to resolve what I believe to be the most serious problems concerning notification. My proposal is designed to ensure that notification will only take place when there is a reasonable scientific basis for it.

Further, my proposal is designed to limit the liability problem that any notification program is bound to generate.

I believe that disposition of the liability concerns is essential if we are to be able to pass legislation of this nature.

My bill is based on two key principles. One, notification is appropriate and should take place when there is a reasonable scientific and medical basis for it; and two, a disease notification program should not serve as the basis for establishing the liability of an employer for an occupational health hazard, nor should it have any bearing on tort or workmen's compensation claims for harm resulting from an occupational health hazard.

In brief, S. 638 is designed to establish a mechanism to provide for the appropriate notification to individuals at a significant risk due to exposure of a hazardous substance or agent.

I look forward to the testimony and comments of our witnesses today.

I will at this point insert the prepared statement of Senator Hatch in the record.

[The prepared statement of Senator Hatch follows:]

Statement of Senator Orrin G. Hatch
Before Labor Subcommittee Hearing on
The High Risk Occupational Disease Notification and Prevention Act of 1987

March 9, 1987

We are here today to address an important topic -- when and how to inform American workers about exposure to hazardous substances.

As I mentioned at our first hearing, there seems to be a consensus in this Committee that a worker who has been exposed to a hazardous substance should be informed of that fact when successful medical intervention is available. Unfortunately, the implementation of this simple principle is very complex.

Senator Metzenbaum and Senator Quayle have both introduced bills which make good faith efforts to address this problem and both should be commended. Senator Quayle would use the traditional peer review process to evaluate appropriate studies and trigger notification of the study subjects and other similarly situated individuals.

Senator Metzenbaum would require every worker who may have been exposed to a potential occupational health hazard within the last 30 years to be located and notified of that fact by either the federal government or the employer. Once located, the employer would be required to furnish medical monitoring for the rest of the employee's life.

This Committee is now evaluating who will benefit from and what the cost will be of these proposals. At a time when America is struggling to become more competitive, the last thing we want is to place a large burden on American business, without a payoff in the form of improved health for American workers.

During our first hearing, one thing was clear. We don't yet have answers. We don't know how many people will be effected by this legislation. Some have said as few as 100,000 people a year, other estimates range up to 23% of the American population, over 50 million people. More importantly, we don't know how many people will be helped by this legislation. We're told that these workers need to be encouraged to stop smoking, something we ought to be telling everyone, but we have not been told of any other benefits from this investment.

And what about the costs? We heard an estimate of $20 million a year. It seems to me that someone either lost some zeros or mistakenly replaced a "B" with an "M". The Carter Administration studied this issue back in 1977 and they estimated that it would cost $54 billion dollars to implement a similar, but more limited program. We also were told at our last hearing that the cost of providing the first medical evaluation to workers exposed during one year, to one occupational health hazard (silica dust), would be well over one-quarter of a billion dollars.

It would be irresponsible for Congress to enact any piece of legislation without fully understanding both its benefits and its consequences. In this case we so far know neither.

I hope this series of hearings will provide carefully considered answers to these questions. My colleagues and I are working to answer them in ways which protect both the workers and, just as importantly, their jobs.

Senator QUAYLE. I am very pleased to have two scientists the caliber of Dr. Burger and Dr. Higginson who are able to join us. I realize that both of you made considerable adjustments in your schedules to join us today, and I want to extend my appreciation to both of you.

Dr. Burger is currently the Director of the Institute for Health Policy Analysis at Georgetown University Medical Center. His very distinguished career includes many years on the faculty at both the Harvard School of Public Health and Georgetown Medical School and on the staff of the President's Science Advisor. In recent years, he has added to his activities a study of the use of science in the judicial system, and he can be credited for organizing one of the premier conferences in the country on the issue of causation in toxic tort litigation.

Dr. Higginson is also with the Institute of Health Policy and Analysis at Georgetown. He is also currently on the faculty of both Georgetown Medical School and is a Professor of Epidemiology at the University of North Carolina. We are particularly pleased to have Dr. Higginson with us today because of the 15 years he spent as Director of the International Agency for Research on Cancer, in Lyons, France, which publishes the monograph series on cancer and is, I think everyone can agree, the "bible" of chemical carcinogens.

I am also pleased to welcome representatives of the American Industrial Health Council—Dr. Hoerger, Chairman of the Science Policy Committee, and Dr. Reape, Chairman of the Epidemiology Committee. The American Industrial Health Council is an industrial association whose primary purpose is to utilize its expertise to strengthen the scientific basis for public health policy.

Dr. Burger, welcome, and would you please begin?

STATEMENTS OF DR. EDWARD J. BURGER, JR., DIRECTOR, INSTITUTE FOR HEALTH POLICY ANALYSIS, GEORGETOWN UNIVERSITY MEDICAL CENTER, ACCOMPANIED BY DR. JOHN HIGGINSON, DIRECTOR, UNIT OF ADVANCED STUDIES; AND DR. FREDERICK HOERGER, CHAIRMAN, SCIENCE POLICY COMMITTEE, AMERICAN INDUSTRIAL HEALTH COUNCIL, ACCOMPANIED BY DR. MARTIN REAPE, CHAIRMAN, EPIDEMIOLOGY COMMITTEE

Dr. BURGER. Thank you, Mr. Quayle.

I appreciate the opportunity to appear before you this morning. The subject the Senate and this Committee are addressing is one of substantial national importance, in my view. There can be no reasonable issue taken with the concept that the citizenry, including members of its working force, should be as fully as possible knowledgeable of the nature of hazards that surround them.

Further, and fundamental to my profession, recognized opportunities for the prevention of disease and disability should be seized wherever they appear.

The specific issue of this hearing concerns opportunities and obligations for notification of workers of the findings of scientific inquiries concerning occupational risks. The issue has had, as this Committee knows, as legacy of thought and inquiry which should be looked to in crafting any legislative initiative.

The issue began some years back. Its prominence arose, quite correctly, as you pointed out, from a consideration of what to do with the results of studies performed on groups of occupational workers. The initial challenge concerned when and how to transmit positive and negative findings to employees, employers and others resulting from studies of worker populations, and to survivors in the case of retrospective mortality studies.

This point is worthy of emphasis. The initial thrust of both the professional and public concern turned around findings or studies performed on humans. The general thrust of the legislative proposal, S. 79, is consonant with the principal medical and social goals of notification discussed by others. However, certain details of the bill are sufficiently flawed as to threaten to undermine those very social goals it seeks to achieve.

I am confident that they can be remedied, but they require special attention.

Because of my professional background, I will concentrate on the medical-scientific issues of this matter and the implications of this legislation for health. Here, I believe it important to review briefly some of the attention afforded this issue by some of the nation's best scientific talent.

In 1977, the National Institute of Occupational Safety and Health embarked upon an inquiry concerning the notification of survivors of the results of positive findings from studies performed on specific groups of workers. The particular focus was on scientific and medical issues and on opportunities for prevention of disease.

At the same time, the inquiry acknowledged that narrow medical-scientific issues were inevitably linked to broader ethical, legal and social questions.

Between 1977 and 1980, NIOSH sponsored two pilot studies of individual worker notification. During the period 1977 to 1980, notification was the subject of a substantial amount of serious consideration among physicians and scientists professionally dedicated to the study of occupational disease, often in the company of ethicists and lawyers—in and out of government.

A recurrent issue central to all of these discussions was the importance of validity of the diagnostic and prognostic message in notification and ultimately, the vitally important quality of the medical-scientific background for making a determination to notify.

This important issue was the subject of a series of excellent and very thoughtful commentaries and analyses published in the professional literature during this time.

In May 1986, the Board of Scientific Counselors to NIOSH, a group of distinguished advisors to the government, developed a set of guidelines or criteria for notification of workers following upon findings from population studies of occupational groups.

Again, great emphasis was placed on assuring that the decision to notify and the choice of notification route were based on a sound, scientific, factual basis. To establish the quality of the factual basis, the advisory body urged that the data used by drawn from studies which were appropriately designed and analyzed and that findings used be biologically plausible and consistent with other biological and medical evidence. Guidelines for determining seriousness of risk and, therefore guidelines for degree and depth of notification, should take account of both relative and absolute levels of risk. Three levels of notification were proposed reflecting levels of seriousness of risk.

The Board of Scientific Counselors emphasized the importance of using these guidelines flexibly when designing the plan for notification. Because I believe this body of scientific thinking on the matter of notification is of such value to the Committee, I would like to request that a copy of the report of the Board of Scientific Counselors be inserted into the record of this hearing.

Senator QUAYLE. It will, Dr. Burger. Thank you.

Dr. BURGER. Why do I emphasize this matter of quality and correct interpretation of the medical-scientific factual material underlying the decision to notify?

As I pointed out at the outset, one of the important tenets of my profession is that opportunities for prevention of disease should be seized. Another is "above all, do no harm." There is a possibility in every experimental medical study of reaching both false negative conclusions-that is, persons or groups who have a disease but are not recognized as such-and false positive conclusions-that is, persons or groups incorrectly identified as having been made ill by the exposure in question.

The false positive question is a serious challenge. As one thoughtful commentator observed, "A person notified of a risk but who does not develop the disease has as many of the same needs as one who does."

This raises the question of the needs of those notified. This is a serious matter and deserves explicit consideration in any legislation which statutorily mandates notification. All of those who have commented on this matter have noted that notification as an endpoint by itself is socially inappropriate or even irresponsible.

Raising the specter of possible or probable disease or premature mortality brings with it the inevitable necessities of medical and social follow-up and further medical surveillance. The cost of these and the responsibility for their execution deserve much more than the cursory attention they have been afforded to date.

The proposed legislative initiative, S. 79, recognizes the importance of hazards to health in the workplace. It acknowledges the importance to society of understanding by its working members of the riskiness of their environment and, hence, of notification. It outlines a mechanism to review significant positive scientific findings as a basis for a decision to notify. It proposes a mechanism—Board of Technical Experts—to help judge scientific data and assess risk. It inserts a specific mandate to perform added research and monitoring of occupational hazards.

I believe that this is a good beginning. However, to make it workable, useful, and to assure that it will not do more harm than good, certain important features, I believe, should be addressed.

On the matter of quality and meaning of scientific data, the spirit of this bill is to trigger a process of notification on the basis of essentially any type of data of whatever source, type or scientific quality. Note that this issue began with a concern for population studies—especially retrospective mortality studies. To move to a process of notification triggered by any type of data raises serious concern and the possibility of substantial numbers of false positives.

The concept, statistically significant evidence based on as few as one single study, simply will not square with any body of responsible scientific thinking.

The concept of a Risk Assessment Board is eminently valid and can draw from similar experience in this country and others. However, an essential ingredient in its success is membership by a group of experts drawn from outside the government—outside the government—and chosen for their recognized contribution to science and medicine.

Since the method of choosing this body will be important, it may once again be expedient and wise to turn to a body such as the National Academy of Sciences for nominations.

Finally, this advisory body will require additional scientific talent from time to time, specifically expert in the particular hazards and studies under consideration. Provision should be made for consultant or working committee arrangements.

An important early task for the Board will be to develop criteria and guidelines for notification. Much homework has already been done and further efforts should build on that experience. New guidelines should take into account the pivotal importance of quality and interpretation of medical-scientific evidence. All of this must be done with an explicit concern for broader issues, particularly ethical issues involved in notification. Above all, the ultimate notification process must do no harm.

The bill is relatively silent on the important issues of medical follow-up and later or continued surveillance. Accommodation will require special handling and involve substantial costs. There are some who consider this a serious flaw—perhaps sufficiently serious to propose a delay in its enactment until these costs and arrangements are developed and refined.

The bill contains in effect a quota for notification. That is a highly objectional feature and would seem to have no place in a piece of social legislation of this sort.

Finally, although I had promised to address the medical-scientific issues raised in this proposal, I feel it important to consider the relative matter of legal liability flowing from this initiative.

The Institute for Health Policy Analysis, which I direct, has been deeply immersed in the complex of financial compensation for disease, tort liability, and the intersection between science and the law. In this, we have been much concerned with the scientific and legal concepts of causation and the linkages between scientific findings and legal judgments.

Here, I join some others in confidently predicting an increase—perhaps a substantial onslaught—of new litigation from this legislation in its present form. Since the court consistently appears to be an inappropriate avenue for either seeking compensation or for finding scientific truth, I cannot welcome that outcome. It certainly will not further the spirit of this proposal of preventing disease.

Some shield appears necessary in order to assure that the primary goals of this legislation are met and not diluted by other, frankly undesirable, outcomes. Accordingly, I would strongly urge consideration of insertion of language comparable to that found in section 399 of your proposal, S. 638, The Health Risk Notification Act of 1987. It may be desirable to further strengthen that section to the effect that none of the medical-scientific data which constitute the substance of notification can be introduced in evidence in a legal proceeding for damages or for compensation.

We would be pleased to work with you and your staff to further refine this proposal. I would be pleased to answer any questions.

Thank you.

Senator **Quayle**. Thank you very much, Dr. Burger.

[The prepared statement of Dr. Burger and the report of the Subcommittee on Individual Worker Notification of the Board of Scientific Counselors follow:]

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Testimony of

Edward J. Burger, Jr., M.D., Sc.D.
Director
Institute for Health Policy Analysis
Georgetown University Medical Center
Washington, D.C.

Before the
Subcommittee on Labor
Committee on Labor and Human Resources
United States Senate

March 9, 1987

My name is Dr. Edward J. Burger. I am a physician an scientist with particular training in the field of preventive medicine. I am the Director of the Institute for Health Policy Analysis, Georgetown University Medical Center. My background includes a Doctor of Medicine from McGill University and a Doctor of Science from Harvard. For nearly a decade I served on the faculty of the Harvard University School of Public Health where I was engaged in research and teaching in a department dedicated to the study of the biological mechanisms underlying environmentally-caused disease. During the early 1970's, I served in the White House Office of Science and Technology -- the staff of the President's Science Advisor.

The subject the Senate and this committee are addressing is one of substantial national importance. There can be no reasonable issue taken with the concept that the citizenry, including members of its working force, should be as fully as possible knowledgeable of the nature of hazards that surround them. Further, and fundamental to my profession, recognized opportunities for the prevention of disease and disability should be seized wherever they appear.

The specific issue of this hearing concerns opportunities and obligations for notification of workers of the findings of scientific inquiries concerning occupational risks. The issue has had, as this committee knows, a legacy of thought and inquiry which should be looked to in crafting any legislative initiative. The issue began some years back. Its prominence arose, quite correctly, from a consideration of what to do with the results of studies performed on groups of occupational workers. The initial challenge concerned when and how to transmit positive (and negative) findings to employees, employers and others resulting from studies of worker populations, and to survivors in the case of retrospective mortality studies.

This point is worthy of emphasis. The initial thrust of both the professional and public concern turned around findings or studies performed on humans. The general thrust of the legislative proposal, S. 79, is consonant with the principal medical and social goals of notification discussed by others. However, certain details of the Bill are sufficiently flawed as to threaten to undermine those very social goals it seeks to achieve. I am confident that they can be remedied but they require special attention.

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A recurrent issue, central to all of these discussions, was the importance of validity of the diagnostic and prognostic message in notification and, ultimately, the vitally important quality of the medical-scientific background for making a determination to notify. This important issue was the subject of a series of excellent and very thoughtful commentaries and analyses published in the professional literature during this time.

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We would be pleased to work with you and your staff to further refine this proposal. I would be pleased to answer any questions.

UNIVERSITY OF CALIFORNIA, IRVINE

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May 20, 1986

J. Donald Millar, M.D.
Assistant Surgeon General
Director
National Institute for Occupational Safety and Health
1600 Clifton Road N.E.
Atlanta, Georgia 30333

Dear Dr. Millar:

Enclosed is the revised report of the Board of Scientific Counselors Subcommittee on Individual Worker Notification. The report was revised in response to comments received. We transmit this report to NIOSH as representing the sense of the Board on this important and complex subject. While every Board member may not agree totally with every detail in the report, we believe that it represents fairly the majority of opinions of the Board, and we hope that it will be of assistance to NIOSH in dealing with this difficult subject. Although we recommend adoption of this notification program, we are aware of the costs of implementation, and do not recommend implementation at the expense of ongoing programs of NIOSH.

If you have any questions, please let me know.

Sincerely yours,

James L. Whittenberger

James L. Whittenberger, M.D.
Chairperson
Board of Scientific Counselors

Enclosure

REPORT OF THE
SUBCOMMITTEE ON INDIVIDUAL WORKER NOTIFICATION
NIOSH BOARD OF SCIENTIFIC COUNSELORS

February 15, 1986

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NIOSH Board of Scientific Counselors
Subcommittee on Individual Worker Notification
Meeting Report
October 18-19, 1985

INTRODUCTION

The Subcommittee on Individual Worker Notification met on Friday and Saturday, October 18-19, 1985, to discuss the proposed NIOSH decision logic for selecting the retrospective cohort mortality studies of which the individuals should be notified. Members of the Subcommittee and outside consultants to the Subcommittee are listed in Appendix 1. As an introduction for the subcommittee, NIOSH staff presented the following information:

> The National Institute for Occupational Safety and Health (NIOSH), in accordance with the Occupational Safety and Health Act and the Federal Mine Safety and Health Act, conducts a wide range of research activities on health and safety issues related to the workplace. In many cases, NIOSH provides notification of the study results directly to the individuals involved. For example, in health hazard evaluations, which are requests by employers or employee representatives for assistance at the worksite, NIOSH sends results of the studies to the requester, the company involved, employee representatives, union headquarters, the Department of Labor, and appropriate State agencies. In addition, final reports are either posted at the worksite for 30 days or are sent to the affected employees. The results of any medical tests performed on individuals are reported directly to the individuals themselves and to the health care provider designated by the employee. Every year NIOSH conducts approximately 550 health hazard evaluations involving thousands of employees and, in each instance, follows these practices routinely.
>
> For epidemiological studies other than health hazard evaluations (such as mortality studies), NIOSH also follows the above procedures with the exception that results are not posted at the workplace (because the involved businesses are frequently multiple and in many locations) nor sent to the affected employees unless medical tests were performed. For all medical tests, NIOSH reports the results directly to the individuals and the individuals' designates.
>
> Public attention has been focused on the Institute's individual worker notification policy for the type of epidemiologic study called the retrospective cohort mortality study. These cohort studies involve a review of records from various sources but very rarely involve direct contact with individual workers. In fact, NIOSH does not usually receive information about an individual worker that the company or the worker does not already have. Essentially, these are statistical epidemiologic studies in which NIOSH extensively analyzes all available data on the research

topic. From the data gathered, NIOSH develops general, aggregate information about trends and potential risk factors for groups of workers. NIOSH provides these aggregate data to the companies, to other sources that have provided records for review, to relevant unions or employee representatives when they exist, and to the Department of Labor and appropriate State agencies. The findings are also distributed through the general scientific literature and through special publications that are available to the public and the media. Any company or union may inform current or previous employees of the study results. The degree to which aggregate information analyzed for a cohort, may be applicable to any individual in the cohort, is a major, and unresolved, issue.

NIOSH has considered the important issue of whether or not individual workers who were included in cohort mortality studies should be individually notified of the results of the study, and how they should be notified. The Institute has concluded that in general, these workers should be individually notified where a significant risk was identified by the study. Major issues as yet unresolved are what is a "significant risk," which cohorts should be notified, and how this should be done? The measures ultimately selected, must be prudent and compassionate so as to minimize any adverse consequences to the workers receiving the information.

NIOSH has developed a "decision logic" for determining which study cohorts should be selected for notification. Obviously, it is imperative that the decision logic be scientifically sound. Therefore, a review and assessment of the scientific quality and appropriateness of the proposed "decision logic" and its application is needed.

Background

Since 1977 questions have been raised about whether the surviving subjects of cohort mortality studies should be notified of study results (1) because they have a right to that information; (2) because NIOSH has an obligation to inform them; or (3) because both a right and an obligation are involved.

The opinion of the HHS Office of General Counsel is that currently there is no legal responsibility for NIOSH to notify these subjects. The CDC Ethics Committee has also considered this issue. Although it has not produced a final report, the draft report accepts the basic view that some risk circumstances create an obligation to inform, particularly when NIOSH is the exclusive holder of data, and when there is clear evidence of a cause-and-effect relationship between an exposure and a health risk.

In 1977 the issue of worker notification was raised in hearings before the Subcommittee on Labor of the Senate Committee on Human Resources. In response to questions about NIOSH'S practices, the then Director of NIOSH, Dr. John Finklea, indicated that NIOSH ensured in a variety of ways that research results were widely available to management, labor, academia, and in the public domain, but that the Institute did not notify individual subjects of results because (1) many of the logistical issues pertaining to individual worker notification were unresolved; (2) the high cost of notification had to be considered; (3) there is a need for subsequent medical surveillance after notification and such medical surveillance is not within the purview of NIOSH; and (4) there are problems inherent in notifying individuals when no effective early detection method is available. Although not voiced specifically at the hearings, there was internal concern among some NIOSH employees that findings from cohort mortality studies might not be pertinent to the risk status of individuals.

Subsequent to the 1977 hearings, NIOSH has embarked on various projects aimed at evaluating the problems of notification and identifying possible solutions. In 1977 a report entitled "Practical Problems and Policy Issues Arising from Exposures to Hazardous Chemicals and Physical Agents in the Workplace" was submitted to the Senate Subcommittee. This report was a first step in providing an overview of the problems inherent in individual worker notification.

In 1979, NIOSH completed a small pilot study of individual worker notification of a selected group of 55 terminated workers, whose medical records had been submitted to NIOSH pursuant to the provisions of the Occupational Safety and Health Act and the Occupational Safety and Health Administration's regulations on 13 carcinogens (29 CFR Part 1910.10). The workers were sent letters that told of possible exposure to a carcinogen. No medical surveillance or follow-up was planned. Forty-nine percent of those who presumably received a letter responded by asking NIOSH to send medical information to their physician. However, on the basis of a telephone survey, none were known to have contacted their physician. It was estimated that the cost of this notification alone was about $150 per worker notified.

In 1980, a major pilot study was begun (1) to evaluate the problems inherent in notifying individual workers of their potential health risks, and (2) to identify criteria and develop a conceptual model for subsequent notification efforts. A cohort of 1,385 workers exposed (in Augusta, Georgia) to a potent bladder carcinogen, beta-naphthylamine, was selected. Of this original cohort, 1,094 were believed to be alive and potentially locatable at the time of the study and were notified by mail of their potential risk. Our best estimates indicated that 849 workers actually received notification. In collaboration with State and local health departments, a local medical college, and a community action group, a bladder cancer screening program and an education program were established with 655 workers participating. Four new cases of bladder cancer were found as a result of the notification program. Fourteen cases were found in all--3 from death certificates and 7 cases were detected and treated independently from the notification effort. This study showed that individual worker notification is merely the first step in a long and complex process. It confirmed that notification can be achieved, but that there is a need for subsequent provision of information, for medical surveillance, and for support programs for those notified and sometimes for their families.

The Augusta study also included an evaluation of the assumptions implicit in a notification program, and more specifically it addressed the questions of whether the results of epidemiological studies were applicable on a individual clinical basis. It was concluded that for the workers in this study such information is applicable.

Within the Institute there is no single list of people at risk; rather, there are records of a variety of study types with divergent results that need individual evaluation as to whether there might be potentially notifiable risks. A working group within NIOSH has inventoried all previous and ongoing NIOSH epidemiological studies and has categorized them roughly into groups that might be candidates for notification.

Subcommittee Charge

What NIOSH requested from the Board of Scientific Counselors Subcommittee on Individual Worker Notification was a review and assessment of the scientific quality and appropriateness of the proposed "decision logic".

Specifically the charge was:

1. Review the scientific validity and consistency of the NIOSH "decision logic", and
2. Review the application of that "decision logic" to a group of epidemiologic cohorts so as to evaluate the propriety of the implementation of the "decision logic".

The charge to the subcommittee concerned the possibility of additional notification of individuals involved in retrospective cohort mortality studies. Currently, this involves companies and local union representatives and appropriate State agencies which are notified about the results of these studies. It should also be noted that the subcommittee was only requested to review criteria for individual notification of cohort mortality studies. NIOSH has also collected data which define groups at high risk based on cross-sectional medical studies case control studies and on industrial hygiene studies. Separate criteria will need to be developed for these groups.

RECOMMENDATIONS TO DIRECTOR, NIOSH

The purpose of the meeting was to conduct a scientific review of the "decision logic" and to review its application at a later date. After the one and one half days of deliberation regarding the NIOSH decision logic the following recommendations are made to the NIOSH Board of Scientific Counselors to be forwarded to the Director, NIOSH.

Retitle the decision logic to "Guidelines for Notification of Individual Workers".

These guidelines are meant to be flexible and applied on a case-by-case basis. We must stress that these recommendations are meant to be guidelines; they are not to supplant scientific interpretation and judgment. The cohort studies under consideration are complex and we consider it inappropriate to apply simple, rigid rules to complex studies.

A. Determine that the study is appropriately designed and analyzed.

The study needs to be carefully reviewed in the context of questions such as:

1. Was an appropriate hypothesis formulated for the study?
2. Was the study population appropriate and of sufficient size to address this hypothesis?
3. Is there adequate documentation of cohort selection? Could this selection be biased?
4. Was there adequate follow-up of the cohort?
5. Were the causes of death adequately documented particularly for diagnoses where death certificate data needs confirmation?
6. Were appropriate statistical methods used to analyze the collected data?
7. Are the risk estimates from the study reliable? The determination will include confirmation of the definition of the study groups and the confidence of the study results.

All of these factors (and others) need to be reviewed in determining whether the study is appropriately designed and analyzed.

B. Consider whether the findings are consistent with those of other studies.

The study results then should be reviewed to determine whether other information supports the conclusion of the study. This other information may come from animal studies, other human health studies, accepted mechanisms of action and metabolism to substances having similar activities. Biological plausibility should also be considered. Findings consistent with this other information would be likely candidates for notification. A finding not supported by other studies would need much greater evidence of elevated risk to be considered for individual notification.

C. Establish whether the survivors are or are not at risk.

Another important aspect of a notification decision is a determination that the survivors are still at risk from their previous exposure. Often the lack of information will make this difficult to determine, and the cohort will have to be assumed to still be at risk. However, in some instances, a change in production process control or a substitution in the process will place a subpopulation of the cohort survivors at much less risk than cohort members who worked prior to the change. This will have to be very carefully determined before deciding not to notify on this basis.

Another consideration is that of the selection of only certain cohort groups for notification. In some cohort studies it may be possible to identify a portion of the cohorts who are at increased risk as compared to others in the study. This selection will usually be based on work in certain areas of the plant with unique or much greater exposure to the toxic substance. This differential notification will have to be very carefully reviewed prior to leaving certain cohort members out of the notification process.

D. Determine that the cohort has not been previously notified.

The review of each cohort study must also address whether the cohort has already been notified. This may have been done through special screening programs at the plant or other efforts. If over seventy five percent of the group has already been notified no further notification is proposed. As with other criteria, this cut off must be judged with flexibility. The nature of the previous notification effort, the information included in that notification and its timing would need to be assessed.

E. Notification Options: The following options are sufficient but not necessary criteria to trigger notification actions. Other factors to be considered include the potential for medical intervention (treatable disease) or other steps which would alter the eventual individual risk. Also, it is important to reduce false negative and false positive notifications.

1. If the attributable risk[1] is at most 25 percent (or the SMR[2] is greater than 133), and the absolute risk[3] is less than 10^{-5}, then:

    a. Employers and union representatives for the same type of industries should be notified of the results through a general notification effort.

    b. The cohort should be notified through information on the study being provided to the involved company and union officials and, where possible, posting of the report in the involved locations.

2. If the attributable risk is between 25 and 50 percent (or the SMR is between 133 and 200) and the absolute risk is between 10^{-3} and 10^{-5}, then:

    a. Notify the involved industry and unions as outlined in E.1. above.

    b. NIOSH Alert: Through appropriate mechanisms such as a Hazard Alert, NIOSH should take active steps to notify the industry and work force of the hazard.

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[1] As used here, attributable risk (AR) is synonymous with the terms attributable risk (exposed) or attributable fraction (exposed) as defined by JM Last in A Dictionary of Epidemiology, p.7. The definition as adapted to mortality studies is as follows: In a situation in which exposure to a given factor is believed to cause a given outcome, the attributable risk among the exposed is the proportion of the outcome among those exposed to the factor that can be attributed to the exposure factor. In these guidelines, it will be expressed as a percent. It is computed as: AR = (SMR-100)/SMR. For example, if the SMR for a specific disease is 133, the AR would be (133-100)133 = 0.25 or 25%. If information on other risk factors was available, appropriate adjustments in attributable risk could be made. However, this other information is usually not available.

[2] The Standardized Mortality Ratio (SMR) is the ratio of the number of deaths observed in the study population to the number of deaths expected if it had the same rate structure as the standard population. An SMR that is greater than 100 indicates an excess of observed deaths in a study populations.

[3] As used here, absolute risk represents the actual risk in a population, that is, the probability of cause-specific deaths occurring within the lifetime of the population. Absolute risk is expressed here in a shorthand form according to orders of magnitude. For example, an absolute risk of less than 10^{-5} means that the risk of dying of a given disease in a population during its lifetime is less than 1 in 100,000.

c. Notify the local newspapers and media in the areas where the cohort is located of the findings of the study and the implication of these findings for the study participants.

d. Notify the appropriate public health agencies.

3. If the attributable risk is greater than or equal to 50 percent, (or the SMR is greater than 200) and the absolute risk is greater than 10^{-3}, then individual worker notification will include:

   a. Efforts to locate individual members of the cohort.

   b. Individual letters of notification to the cohort participants informing them of their assumed increased risk.

   c. Notification of noncohort workers which will be the same as E.1 and E.2.

   d. Appropriate provision for workers to contact NIOSH personnel to obtain further information.

When considering this option and when individual worker notification takes place under E.2., the provisions for support services in connection with notification must be thoroughly evaluated before proceeding.

Note: The three options do not cover all possible combinations of absolute and attributable risk. When studies have risk combinations that do not meet the options as described great care should be taken to ensure the appropriate worker notification option is applied.

F. Other Recommendations

In considering the above guidelines, again flexibility and case-by-case decision making are to be utilized. Additional considerations that the Director of NIOSH should use for the individual decisions include:

1. When considering the SMR the comparable population should be reviewed carefully. National statistics may not always be appropriate.

2. Attributable risk as defined should be given greater weight than the other criteria.

3. The setting of a limiting statistical p value is probably not appropriate for this use.

4. Adjustment for simultaneous inference should be used cautiously and only if the unadjusted estimates of probability are also presented.

5. Individual worker notification as described in E.3. would be used if worker notification as described in E.2. is not possible because the plant is closed and the cohort is geographically dispersed or if selected groups within the cohort have a much higher risk.

6. Decisions regarding individual worker notification after the guidelines have been applied by NIOSH to their studies should be audited by an external peer review group.

7. The notification effort, after implementation should be evaluated for effectiveness. Early efforts should be fully evaluated, with periodic evaluations thereafter. There should be a behavioral scientist on the evaluation team. The primary questions to be answered are:

   a. Were the individual workers notified?, and

   b. What happened after notification?

8. Systems should be in place to deal with health inquiries stimulated by the worker notification and to provide health care as may be appropriate.

9. There should be a disproportionate use of resources for those subjects of cohorts at greater risk.

In summary, the Subcommittee recognizes that there are different levels of intensity of notification and that there should be different criteria for each. The Subcommittee appreciates the uncertainty implicit within the guidelines, on the other hand, the Subcommittee believes the guidelines are necessary and valuable to a thoughtful, careful review of the cohort studies. Both the NIOSH internal review committee and the external peer review committee have the flexibility to reclassify a study cohort. Again the Subcommittee is especially concerned about minimizing both false negatives and false positives.

Some of these recommendations are made with the knowledge that they may exceed the authority of NIOSH. When this occurs every effort should be made to ensure that worker notification takes place through investigation of alternatives, such as, working with other government agencies.

ISSUES THAT WERE DISCUSSED DURING THE DELIBERATIONS

The members of, and the consultants to the Subcommittee expressed various positions regarding the following issues discussed. The Board of Scientific Counselors should not consider the views expressed as an indication of a Subcommittee position.

A. Objectives of Notification

1. An Ethical Objective of Notification

This objective is limited and is consistent with the draft CDC Ethics Committee report which accepts the basic view that some risk circumstances create an obligation to inform, particularly when NIOSH is the exclusive holder of data, and when there is clear evidence of a cause-and-effect relationship between an exposure and a health risk.

2. A Public Health Objective of Notification

This focuses on the public health consequences of some action. In this situation the argument is to proceed with individual worker notification but to go beyond just the cohorts studied. There was some concern that as a result of the notification effort cohorts, essentially selected at random, would receive the benefits of a screening program or other medical intervention while there may be other workers with similar work experience who are not notified and therefore not accorded the same opportunity. The public health objective as stated goes beyond NIOSH's intent to notify just the involved cohorts.

3. Civil Rights Objective of Notification.

This focuses on the right of all persons in a study to be notified regardless of the study outcome. In essence, individuals who participated in a negative study should be notified with the same effort accorded those who participated in a positive study.

The argument offered is that the three objectives are inextricably linked; that one necessarily leads to the other. The NIOSH proposed decision logic meets the ethical objective but when considering the public health role of NIOSH we are also considering both the public health objective and the civil rights objective.

There was extensive discussion on these three objectives and the impact they should carry regarding the NIOSH proposed decision logic. The dichotomous positions were 1) full notification and 2) notification of industry and unions which will assume the responsibility of individual worker notification. The second position argues that industry and unions have the responsibility to protect workers and rightfully they should bear the burden of individual worker notification, not government. There was no resolution to this debate but the Subcommittee took it into consideration when making its recommendations.

B. Minimum Notification

An issue closely linked with the civil rights objective is the issue of minimum notification. The argument being that consistent with the civil rights objective all workers should be notified albeit at varying levels of intensity of effort. Notification efforts would be made for cohorts of studies with negative results or very low risk. The Subcommittee believed the benefit to be marginal and the costs in anxiety generated, medical cost, litigation, and the diversion of resources that could be put to better use elsewhere, to be too high so that no recommendation for minimum notification was made.

C. Application of Group Data to Individuals

Another broad issue is that NIOSH is proposing to take aggregate data and apply it to the individual case. Retrospective cohort mortality studies conducted by NIOSH investigate groups for the purpose of contributing to development of public health knowledge and the Federal government's standards development process. The notion of individual worker notification requires taking group data and applying it to the individual case. There is a threefold concern:

1. Is it valid to take epidemiologic data and apply it to the individual case?

2. Are the thresholds within the "guidelines" valid for the individual case (i.e., rigid adherence to the criteria)?

3. Are the criteria for decisions made within the realm of public policy (i.e. standards development) appropriate in the individual case?

This is of particular interest when considering absolute risk levels. Such criteria are used for development of regulations and have never been discussed regarding individual assumption of risk and the concomitant effort of individual worker notification. Again, these were taken into consideration during deliberation.

D. Ethical, Social, and Economic Issues

The Subcommittee believed that ignoring ethical, social, economic, and other considerations was not possible. While the Subcommittee agrees that the general process of worker notification is sequential, the specific events are interrelated and should not be treated as mutually exclusive. Given that events are not mutually exclusive, then a NIOSH proposed decision logic cannot be reviewed without also considering the method of notifying individual workers.

There was general agreement that the NIOSH proposed decision logic should be "coupled" with the form of the message. We must recognize that there is a spectrum of options for notification and to ignore the form, to narrow the focus of the discussion on only the NIOSH proposed decision logic, will not stand the test of public scrutiny. The decision of the Subcommittee was to address both the NIOSH proposed decision logic and the method of notification.

E. Rigid Criteria Versus Flexible Criteria

The Subcommittee believed the decision criteria should be flexible. Retrospective cohort mortality studies, by their very nature, are complex studies. For instance, determining true excess risk, determining confidence intervals, accounting for cofactors or confounding variables, and minimizing biases make definitive results difficult. The Subcommittee believed that there was no random sampling and recommended against reliance upon the p value as a firm criterion to be used in the NIOSH proposed decision logic.

Generally, the Subcommittee believed that there was a need for more flexibility in the NIOSH proposed decision logic allowing for interpretation and judgment. The idea of sufficient but not necessary criteria to act as guidelines for deciding on the appropriate notification effort was very appealing to the Subcommittee. These sufficient but not necessary criteria would be used by an internal NIOSH committee to review the cohort studies and make a recommendation regarding notification. Superimposed on this structure would be an external committee to audit the decisions of the NIOSH internal committee to ensure appropriate use of the criteria.

F. Media Impact

The role that the media plays in the process of individual worker notification was left unresolved. The incremental benefit contributed by the media is a question that may warrant further attention. Based on the experience in Augusta, where individual workers were notified by the media prior to receiving the NIOSH letters, it is conceivable that the NIOSH proposed decision logic may in fact not be used for notifying individual workers but to notify the media. Whatever the case, it is clear that a close, cooperative, working relationship must be established with the media to maximize effectiveness and minimize distortion.

TABLE OF INDIVIDUAL WORKER NOTIFICATION OPTIONS

Option 1	Option 2	Option 3
If attributable risk $\leq 25\%$, or SMR ≥ 133, and absolute risk $< 10^{-5}$,	If attributable risk $>25\%$ and $<50\%$, or SMR >133 and <200, and absolute risk $>10^{-3}$ and $<10^{-5}$,	If attributable risk $\geq 50\%$, or SMR >200, and absolute risk $>10^{-3}$,
Then:	Then:	Then:
1. The cohort should be notified through information on the study being provided to the involved company and union officials, and where appropriate, posting of the report in the involved locations.	1. Notify the involved industry and unions as outlined in Option 1.	1. Locate individual members of the cohort.
2. Employers and union representatives for the same type of industries should be notified of the results through a general notification effort.	2. NIOSH Alert: Through appropriate mechanisms such as a Hazard Alert, NIOSH should take active steps to notify the industry and work force of the hazard.	2. Send individual letters of notification to the cohort participants informing them of their assumed increased risk.
	3. Notify the local newspapers and media in the areas where the cohort is located of the findings of the study and the implication of these findings for the study participants.	3. Notification of noncohort workers as outlined in Option 2.
	4. Notify the appropriate public health agencies.	4. Appropriate provision for workers to contact NIOSH personnel to obtain further information.

APPENDIX 1

MEMBERS AND CONSULTANTS TO THE SUBCOMMITTEE ON INDIVIDUAL WORKER NOTIFICATION

Members

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APPENDIX 2

Examples of the Application of the Guidelines to Four Studies

Waxweiler, R. J., et al: Neoplastic Risk Among Workers Exposed to Vinyl Chloride. Ann NY Acad Sci 271:40-48, 1976.

Abstract

The health effects of occupational exposure to vinyl chloride were evaluated in a cohort of 1294 workers at four polymerization plants. Analysis of 136 deaths showed statistically significant SMRs of 149 for all malignant neoplasms and 1155 for biliary and liver cancer. For workers with more than 15 years since onset of exposure, statistically significant SMRs occurred for all malignant neoplasms 134, brain and CNS cancer 498, respiratory system cancer 194, and biliary cancer 1601. Eleven of 14 biliary and liver cancers were angiosarcomas.

Analysis

A. The study is appropriately designed and analyzed.

B. The findings are consistent with other studies.

C. The cohort has not been extensively notified.

D. The SMR for liver cancer is considerably in excess of 300, the attributable risk percent is greater than 50 percent, and the absolute risk is of the order of 10^{-3}; therefore, individual worker notification of this cohort would be warranted. Also found in excess and thus eligible for notification though of lower priority were cancers of the brain, respiratory system and lymphatic system.

Stern, F. B., et al: Exposure of Motor Vehicle Examiners to Carbon Monoxide: A Historical Prospective Mortality Study. Arch Environ Health 36(2): 59-65, March-April, 1981.

Abstract

The National Institute for Occupational Safety and Health (NIOSH) investigated the health effects of chronic exposure to low concentrations of carbon monoxide by conducting a historical prospective cohort study of mortality patterns among 1,558 white male motor vehicle examiners who were employed in New Jersey for a minimum of 6 months between 1944 and 1973. Industrial hygiene surveys indicated that the examiners were exposed to carbon monoxide at a time-weighted average (TWA) of 10-24 ppm; the exposure level recommended by NIOSH is 35 ppm TWA. A modified life table technique was used to calculate cause-specific expected deaths for the cohort adjusted for age and calendar time periods. The expected deaths were compared to the number of observed deaths through August 1973. The cohort demonstrated a slight overall increase in cardiovascular disease deaths (124 observed vs. 118.4 expected), but a more pronounced excess was observed within the first 10 year following employment (28 observed vs. 20.9 expected). A statistically significant excess of cancer mortality was found for motor vehicle examiners after 30 year latency (13 observed vs. 6.9 expected, P < .05); this excess, however, was not confined to any particular organ site. The number of deaths due to accidents was significantly lower than expected (8 observed vs. 19.6 expected, P <.01).

Analysis

A. The study is appropriately designed and analyzed.

B. The findings of an increased attributable risk percent for brain cancer (60 percent) and SMR of 253 would seem to qualify this cohort for notification. However, this finding is not substantiated by other sources and therefore would not warrant individual notification without further study. The same is true for cancer of the pharynx which in this study analysis shows a SMR of 251 and an attributable risk percent of 60 percent.

C. This cohort has not been extensively notified.

D. A review of study results, taken in context with existing research, indicates that further study is needed before a decision for individual notification can be based on the application of suggested criteria.

Robinson, C., et al: Mortality pattern of rock and slag mineral wool production workers. Br. J Ind Med 39:45-53, 1982

Abstract

An epidemiologic and environmental study of rock and slag mineral wool production was undertaken at a plant that has been in operation since the early 1900's. Size characteristics of fibers produced by each process at the plant and industrial hygiene surveys were used to evaluate current and past exposures. These data suggest that the average historical airborne fiber concentration probably did not exceed 2.5 fiber/cc and 1.0 fiber/cc after 1935. A retrospective cohort mortality study was designed to assess mortality patterns. Detailed occupational histories were compiled on all plant employees. All jobs in the plant were assigned to one of eight exposure categories to assess the extent and severity of mineral wool exposure and the effect of other significant exposure on employee mortality. Findings included an increase in the number of deaths due to cancer of the digestive system and non-malignant respiratory disease among workers who had over 20 years' since their first exposure to mineral wool. These findings are not inconsistent with those of Enterline's (Symposium on Biological Effects of Mineral Fibers, Lyon, France, September 1979) in the Thermal Insulation Manufacturers' Association's mortality study of men employed in four mineral wool plants

Analysis

A. The study is an appropriately designed and analyzed epidemiologic study when reviewed within the context and definition of the "Guidelines for Notification of Individual Workers". The cohort, as described, was adequately defined. The data collection and analysis was performed in a manner consistent with accepted epidemiologic practices.

B. These findings are consistent with those of other studies.

C. Survivors continue to be at risk.

D. This cohort has not been extensively notified.

E. The SMR for respiratory disease is 167 with an attributable risk per cent of 40% which would indicate eligibility for individual worker notification through the industry, unions, local media with appropriate public health agencies also being notified. The SMR for cancer of the digestive system is 130 with an attributable risk per cent of 23% which in itself would not trigger a notification effort. However, since both the SMR and the attributable risk are borderline for Option 1 this study would merit careful consideration.

Lemen et al: Cancer Mortality Among Cadmium Production Workers. Ann NY Acad of Sci, 271:273-279, 1976.

Abstract

A study of 292 white male workers at a cadmium smelter was performed to determine their mortality experience. The results of this epidemiologic study show significantly increased mortality due to total malignancies, lung cancer, and prostatic cancer among cadmium smelter workers. These conservative cause-specific results confirm the findings of previous occupational studies and certainly implicate cadmium exposure as the cause of certain type of malignant disease. This finding, in light of the ubiquitous nature of cadmium in our environment, definitely indicates the need for further research and precautionary efforts to reduce environmental exposures to this metal and its compounds.

Analysis

A. The study is an appropriately designed and analyzed epidemiologic study when reviewed within the context and definition of the "Guidelines for Notification of Individual Workers". The cohort, as described, was adequately defined, of sufficient size, and received reasonable follow-up. The data collection was performed in the usual, customary and reasonable manner for such studies and data analysis appropriate.

B. These findings are consistent with findings from earlier studies, as well as, animal studies. However, a recent detailed update found that workers are at risk of lung cancer but not prostate cancer.

C. Survivors continue to be at risk.

D. This cohort has not been extensively notified.

E. The SMR for cancer of the prostate is 347 with an attributable risk per cent of 59% therefore, individual worker notification of this cohort would entail location of cohort members, letters to individuals informing them of their increased risk, as well as industry and union involvement and general media education for noncohort workers.

APPENDIX 3

Minority Opinions

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VICE PRESIDENTS
BILL CASSTEVENS • DONALD F. EPHLIN • ODESSA KOMER • MARC STEPP • ROBERT WHITE • STEPHEN P. YOKICH

November 25, 1985

Elliot Harris, Ph.D.
National Institute for Occupational
Safety and Health
Building 1, Room 3007
Centers for Disease Control
Atlanta, Georgia 30333

Dear Dr. Harris:

I have reviewed the draft report of the Subcommittee on Individual Worker Notification, dated November 15, 1985, and offer the following comments.

I continue to believe that NIOSH should make an organized effort to notify all surviving workers included in mortality study cohorts of the results of these studies. Notification should in all cases be individual, although other supplemental methods should be included in a program in order to assure effective communication. Notification of results should be provided to workers included in all investigations judged to be appropriately designed and analyzed and should not be dependent upon study results.

My views on this matter rest upon the premise that notification of results and notification of risks are related but separate issues. Once it has been determined that a study was competently performed, all cohort members should be equally entitled to the results as an expression of fundamental civil rights in the workplace. The importance and value of these results to individuals should not be prejudged. Having made a threshold decision to notify workers of study results, NIOSH should then make second order decisions about the content of the communication, including judgments or conclusions about risk. The use of decision guidelines (or decision logic) similar to those on pages six and seven of the draft document would be appropriate at this second stage to determine the exact nature, intensity and content of the notification message to various groups. These guidelines would require modification if the principle of universal individual notification were established.

My remaining points are relatively minor compared with the above:

> I think the decision rules on pages six and seven are logically flawed such that certain study groups would completely escape attention. For example, groups with small relative risks (e.g. SMR = 125) but large baseline rates (e.g. cardiovascular disease or lung cancer) would not be placed in any of the notification groups although the public health impact of such risk is considerable.

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The guidelines should allow for other measures of risk such as PMRs or MORs.

The draft does not distinguish adequately between the roles and responsibility of employers and unions.

Stronger provisions are necessary regarding environmental intervention, medical services and related risk management activities with respect to the groups felt to be at highest risk.

In summary, I do not find the current draft acceptable, although I believe it to be a substantial improvement of the original working document provided to the subcommittee. I hope that additional discussion will move the consultants and subcommittee members closer to consensus and will eliminate the necessity for minority statements to accompany the final report to the Board of Scientific Counselors.

Sincerely,

Michael A. Silverstein, M.D.
Occupational Health Physician
Health and Safety Department
International Union, UAW

MAS:mb
opeiu494

cc: Warren Winkelstein, Jr., M.D.

UNIVERSITY OF CALIFORNIA, LOS ANGELES UCLA

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December 3, 1985

SCHOOL OF PUBLIC HEALTH
LOS ANGELES, CALIFORNIA 90024

F. Craig Whiters, Jr.
Program Analyst
NIOSH
Centers for Disease Control
Atlanta, GA 30333

Dear Mr. Whithers,

I have some important concerns about the revised report of the Subcommittee on Individual Worker Notification which, by the way, I find substantially improved.

The major concern is one which relates to the decision guidelines as such. The "cut points" in section E. 1-3, as laid out on pages six and seven, are much too high. I would appreciate some further discussion on this matter but my first proposal would be to reduce the attributable risk percents in all three sections. In the first section I would use 10 instead of 25, in the second 10-20 in stead of 25 to 50 and in the third I would use 20%. The problem is that it would seem to me important to notify a working group of the population risk of a disease if ten percent of it could be attributed to the workplace.

The problem with the application of these guidelines to the examples is also of some concern. In example two the attributable risk percents of 60% and the SMR s of 250 and 251 are concluded not to meet the guidelines because of lack of substantiation. I have not reviewed the information but the supporting documentation does not indicate how much effort was spent looking for substantiation (i.e. more than replication of the findings) and whether the findings are biologically plausible even without replication. I understand that the example was not expected to be an extensive discussion but it would be desirable to know how these guidelines would actually be applied. The proposed oversight function of an external advisory committee would serve a function here (although it too would need more substantial report of the evaluation).

A similar concern is present in example three where SMR and attributable risk percent just under the guidelines is eliminated from consideration because "in itself (it) would not trigger a notification effort". Although literally correct it suggests a problem with rigid application of guidelines. Again, I understand that the NIOSH staff did not intend this to be an extensive discussion of the example but the issues raised by these examples are much more complex than were discussed at the first subcommittee meeting. I believe that the guidelines would benefit from further discussion of these examples to clarify how such a system could actually work.

I have several other and more specific comments which I have described in the following pages, with specific reference to the location in the text of the draft meeting report.

Page 4.

The last sentence in the first paragraph refers to conclusions about the applicability of the Augusta study to individuals. I don't remember this disucssion nor how it was judged applicable.

Page 5. Section A.1.

This could be rewritten to say "Was the study population appropriate and of sufficient size to address this hypothesis."

Page 5. Section A.5.

Add "length of" after "...to both the"

Page 5. Section B.

The last sentence is unclear. Do you mean to say "...much greater evidence of elevated risk..." or "...evidence of much greater risk..." or both?

Page 6. Section C.

I suggest adding the words "unique or" between "the plant with" and "much greater" in the fifth line of the second paragraph on the page.

Page 6. Section D.

I suggest replacing the words "would be needed" with the words "is proposed" in the fifth line.

Page 7. Section E.1.

The intervals, as listed in subsection 1. are not inclusive. I believe the parenthetical statement should read (or the SMR is no greater than 100).

Page 7. Section E.1.b.

I suggest replacing the word "appropriate" with the word "possible" in the fourth line.

Page 7. Section E.2.a.

I have some problem with the language which refers to notify the involved "industry". We have been reviewing the OSHA MIS data on compliance with standards and find an extremely large number of inudstries (categorized by four digit SIC) which have excessive exposure to lead. It is not clear to me that "industry" would be the best identifier of the key concerns. It might be based on users or user associations or some other measure which reduces the number of units receiving the notificaiton to just those who need it.

Page 7. Section E.2.

I am surprised that none of us picked up on an obvious omission from this list. I suggest we add a section: "e. Notify local and state health departments and labor departments".

Page 7. Section E.

The final paragraph of this section states a conclusion which I know was of concern to the NIOSH staff but I believe was not agreed to by the subcommittee. This is not to say that support services are not important but just that their "thorough evaluation before proceeding" was not a conclusion of the meeting.

Page 7. Section F.1.

The statement is correct but it is not suggested how the review process would or could deal with the problem as stated.

Page 8. Section F.3.

I suggest replacing the words "may not be" with the words "is probably not"

Page 8. Section F.4.

I suggest adding to the sentence the phrase: "and only if the unadjusted estimates of probability are also presented".

Page 10 Section B.

I recommend eliminating the last sentence except for the last phrase: "No recommendation for minimum notification was made."

Page 10 Section C.

The word "applying" should be "apply". I would also suggest adding the phrase "to development of public health knowledge and" between the words "contributing to" and "the Federal government's standards" in the fourth line.

Page 10 Section C.2.

I suggest striking the word "statistical".

Page 10 Section D.

What is meant by the word "sequential" in the third line? Also, from this point forth the words "decision logic" are used when we agreed to the term "guidelines".

Page 11 Section F.

I suggest that the word "when" be replaced by the word "where" in the fourth line.

I hope you find these comments useful. I would prefer to have further discussion on several of these points before the report is presented to the Board of Scientific Counselors. Please let me know what further help you need from me.

Sincerely,

cc: Warren Winkelstein

David H. Wegman, M.D.
Professor and Division Head
Environmental and Occupational
Health Sciences

Senator QUAYLE. Dr. Hoerger?

Dr. HOERGER. Thank you, Senator Quayle.

Dr. Reape and I are appearing today on behalf of the American Industrial Health Council. In our corporate responsibilities, I am associated with the Dow Chemical Company in regulatory and science policy matters, and Dr. Reape, in health studies and epidemiology with FMC Corporation.

AIHC appreciates the opportunity to present our views to this Subcommittee. We have four recommendations for your consideration.

The first relates to a strong belief that the notification program should be based upon sound science and ethical considerations. I would like to refer to the NIOSH report, which you and Dr. Burger mentioned this morning, and mention that it served as sort of the genesis for this legislation. It had two important conclusions. One is that worker notification should be based on clear evidence of significant human risk. The second conclusion was that the notification program should be done in a prudent manner so as to minimize adverse consequences.

Dr. Burger has already spoken to those ethical considerations. I would only emphasize them.

The NIOSH Board of Scientific Counselors made one further conclusion, and that was that the epidemiologic information and other scientific information should be carefully scientifically reviewed. We believe that this is an important consideration; such factors as significance of the information, biological and statistical plausibility, the careful evaluation of the exposure of various populations and sub-population groups are of importance in estimated risk potential. Dr. Reape will elaborate on these important considerations in a few moments.

I would summarize this NIOSH report by saying that all of the relevant scientific information should be considered in making a risk determination. We believe that S. 638 conforms to this requirement of sound scientific and ethical evaluation.

On the other hand, we believe that the S. 79 "single-study" criterion is too narrow and confining and is scientifically inappropriate.

Our second recommendation is that a new written notification program should be based on human epidemiological studies. I would like to draw a distinction between animal and human types of information.

Several deliberative bodies—the National Toxicology Program of HHS, the Environmental Protection Agency, and the International Agency for Research on Cancer—draw this distinction between experimental animal studies and human epidemiological studies.

Animal studies are quite valuable in terms of establishing protection standards. In the regulatory context, these animal experiment data are used to assess the possibility of risk and the possibility of risk to population groups rather than to individuals.

This is an important distinction, and there is a real difference between a possibility of risk and a notification of, "You, Mr. X, are at risk."

The distinction is drawn by EPA in their Risk Assessment Guidelines, when they state that their approach to risk assessment basically looks at an upper limit of risk, and they acknowledge that in some cases, the real risk might be actually zero.

I would point out that OSHA has embarked upon instituting a Hazard Communication Standard. We would point out that this standard draws heavily on animal information and requires both notification of employees and training to avoid real risk.

We believe that S. 638 is appropriate in terms of limiting itself to human epidemiological studies.

Our third recommendation, however, does flow from this discussion of experimental animal data. I would point out that the NIOSH study confined itself to principles for evaluating human epidemiological studies. We believe that it would be appropriate for the Congress to authorize a deliberative body, an eminent group, to address this question of experimental animal studies in the new context of worker notification. We would suggest that either the Office of Technology Assessment or the National Academy of Sciences be commissioned for this report, which could then serve as a basis for further Congressional consideration.

Our fourth recommendation is that the structure of the Risk Assessment Board should be such that it would focus on risk assessment and would be composed of independent scientists who can take an objective look at studies and carefully evaluate them. This distinction between risk assessment and risk management functions was drawn by the National Academy of Sciences in a 1983 report, "Risk Assessment in the Federal Government: Managing the Process." The Academy laid out several reasons for differentiating the scientific evaluation from the broader social function of risk management. In this case, we believe that S. 79 should be restructured so as to encompass an independent scientific body which focuses on risk assessment.

The risk management function—that is, implementing the notification program—should be vested in the Secretary with appropriate authority to delegate. In this way, the administrative process incorporating due process would be preserved.

I would like to close my comments by observing that S. 79 and to a lesser extent, S. 638, have considerable potential for overlap of other existing authority. I have mentioned the OSHA Hazard Communication Standard; there is the potential for significant overlap there. S. 79 also has provisions for medical surveillance, worker removal, and rate retention. I would point out that these considerations are a part of the OSHA responsibility when they issue an occupational health standard.

We appreciate the opportunity to make these recommendations, now, with your permission, Senator, I would like Dr. Reape to elaborate very briefly on the scientific considerations.

[The prepared statement of Dr. Hoerger follows:]

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STATEMENT OF

FRED HOERGER, PH.D.
ACCOMPANIED BY
MARTIN REAPE, PH.D.

ON BEHALF OF THE
AMERICAN INDUSTRIAL HEALTH COUNCIL
BEFORE THE
U.S. SENATE SUBCOMMITTEE ON LABOR
COMMITTEE ON LABOR AND HUMAN RESOURCES

MARCH 9, 1987

Introduction

Mr. Chairman, AIHC is pleased to have the opportunity to comment on the scientific aspects of S. 79, High Risk Occupational Disease Notification and Prevention Act of 1987, and S. 638, Health Risk Notification Act of 1987.

My name is Fred Hoerger. I am a regulatory and science policy consultant in the Dow Chemical Company. I am appearing today in my capacity as Chairman of the Science Policy Committee of the American Industrial Health Council. I am accompanied by Dr. Martin Reape, Director of Health Services for the FMC Corporation. He is appearing today as the Chairman of the Epidemiology Committee of the American Industrial Health Council. Following my testimony, Dr. Reape will discuss briefly epidemiologic considerations relevant to the bills.

Description of AIHC

The American Industrial Health Council -- usually referred to as AIHC -- is an industrial association made up of about 70 companies and about 100 affiliated trade associations. AIHC does not act as an advocate or sponsor of any product. Rather, AIHC was formed to utilize the scientific capability of the member companies to develop proposals for strengthening the scientific basis for public health decisions.

AIHC's objective is to enhance protection of the public health by promoting improvement in the scientific bases for identification and control of chronic health hazards such as carcinogens, reproductive toxins and neurotoxins.

AIHC believes that an essential part of a sound occupational health program is to provide scientifically and ethically based notification to workers of significant health risks from occupational exposures.

Our testimony today will address the considerations which AIHC believes are necessary for the development of a socially sound notification program.

Scientific and Ethical Considerations

As the hearings on worker notification last year showed, interest and concern for development of a scientifically and ethically sound program for notifying workers stems from the NIOSH project to develop suitable criteria for notifying individual workers following epidemiologic studies based on medical records submitted to NIOSH pursuant to OSHA regulations. A subcommittee of the NIOSH Board of Scientific Counselors was appointed to develop the logic and criteria for selecting the epidemiologic studies whose findings warranted notification of individual workers. The Report arrived at several conclusions that are relevant to the Committee's consideration of these bills.

- Individuals should be notified when there is a "significant" risk -- when there is clear evidence of a cause-and-effect relationship between an exposure and a health risk;

- The method of notification must be prudent so as to minimize any adverse consequences to workers receiving the information.

The analysis related to human epidemiologic studies based on medical records, technically, a retrospective cohort mortality study. The report also proposed that separate criteria for notification should be developed for cross-sectional medical studies -- studies based on medical evaluation of a representative group of workers. There was no consideration of criteria for notification of workers based on animal studies.

AIHC believes that the ethical concerns referred to in the NIOSH report -- minimize adverse consequences to the person notified -- can be clarified by reference to the primary axiom of medical ethics: "primum non nocere". This latin axiom "do no harm" is more usually understood to have a strong positive element "to help or at least do no harm." Notification can lead to anxiety and stress if not soundly based -- a form of harm that can be serious.

NIOSH recognized that a program based on human studies must address the quality of the data relied on and the nature and extent of exposure of the employees to be notified. The quality of the data is determined by scientific criteria. The study must be appropriately designed and analyzed; the validity and reliability of the underlying information must be examined: was there adequate documentation; was there an appropriate statistical analysis; could a causal relationship be determined and confounding causes eliminated. These and other criteria determine if there is a scientifically valid epidemiologic base for evaluating the nature and character of the human hazard.

The NIOSH study also recognized that reliable information on the nature and extent of exposure was a critical factor in deciding whether there was a reasonable scientific and ethical basis for concluding that there was a significant risk for the individual.

For these reasons we believe that S. 79 is not scientifically sound when it provides an arbitrary criterion using only part of the available data as the basis for decision making. We strongly urge reconsideration of the reliance in Section 3 (7) of S. 79 on "at least one study". S. 638, in contrast, sets forth a number of the considerations involved in sound scientific evaluation of relevant data. Moreover, as scientific understanding advances and new scientific data are developed, the evaluation criteria should permit incorporation of those developments.

We believe that scientific and ethical considerations are essential to a sound individual worker notification program. Dr. Reape will discuss further the scientific considerations relevant to the evaluation of epidemiologic or other human data.

The Distinction Between Epidemiologic Studies and Animal Studies

It is significant that the NIOSH consideration of criteria for notification was based on epidemiologic studies -- actual studies of workers using medical records. AIHC believes there are sound scientific and ethical bases for distinguishing between animal experimental studies and human epidemiological studies in the context of a worker notification program.

Human studies provide a sound scientific basis for a determination that there is clear evidence of a cause-and-effect relationship between an exposure and health risk. Thus, for example, in Annual Reports on Carcinogens issued by the Department of Health and Human Services (The Fourth Annual Report was recently issued), the identification of a substance as a "known" carcinogen is based on a finding of sufficient human evidence of a causal relationship.

Animal data may justify a finding that a substance presents a "probable" or "potential" human risk at some exposure rather than a "known" risk. This in no way derogates from the utility or importance of experimental animal data. Rather, a different kind of scientific analysis is called for when animal data are the bases for evaluation. The U.S. National Toxicology Program that conducts a major cancer bioassay program makes this point clearly in the introductory note to each Technical Report on an animal study. Each Report says:

> The determination of the risk to humans from chemicals found to be carcinogenic in animals requires a wider analysis which extends beyond the purview of this [animal] study." (Our emphasis)

Such a wider evaluation should take into account information and data not included in the animal study. Thus, the evaluation should include available data on the concerned chemical, and the physiological, pharmacological and toxicological differences between the test animal and humans. It would also require a careful analysis of the extent of human exposure -- frequency, duration and intensity.

When a potential human risk evaluation is based on animal data, risk is expressed in "probabilistic" terms: that is, the risk is expressed in terms of a group rather than in individual terms.

Generally, animal experiments are designed for use in establishing standards or criteria for permitted exposure to a substance. In interpreting data from these experiments, a number of prudent assumptions are made in extrapolating high doses to low doses and from animal to man. The resultant probabilistic estimates of risk using current methods are an upper limit of risk, and it is generally accepted that actual population risks are lower and could actually be zero. No estimate of individual risk is made.

This is made clear in the 1986 EPA Guidelines for Carcinogen Risk Assessment:

> "It should be emphasized that the [current] linearized multistage procedure leads to a plausible upper limit to the risk that is consistent with some proposed mechanisms of carcinogenesis. Such an estimate, however, does not necessarily give a realistic prediction of the risk. The true value of the risk is unknown, and may be as low as zero."
> (51 Fed. Reg. 33997-33998)

In other words, current regulatory policies are not based on actuarial risks or an assessment of individual risk.

Let me illustrate. When one evaluates risk in probabilistic terms based on animal data, the risk is usually stated as, for example, one-in-a-hundred thousand or one-in-ten-thousand. The risk is not related to any individual. Translated in individual terms it could be said that a realistic prediction of an individual's risk has potentially increased from 0.0 to 0.00001 or from 0.0 to 0.0001 and could well be still zero. A causal relationship between exposure and an adverse health affect based on animal data is "potential" or "probable" and not "known".

A notification program that is based on experimental animal data, therefore, raises scientific and ethical considerations that are different from those based on human data from epidemiologic or clinical studies. It is important to repeat that the NIOSH study did not address this issue.

I believe it is important to underline that I am in no way denigrating the value of using experimental animal data. The critical factor is the form of notification. We believe the OSHA Hazard Communication Standard is an appropriate method for providing reasonable notice based on experimental animal data. Assessment of the actual risk to an employee requires knowledge not only of the exposure and the scientific data, but equally important it requires knowledge of the worker's medical history and life style including such factors as diet, smoking, and drinking, etc. The information provided under the Hazard Communication Standard is an important part of the necessary data needed to make the medical appraisal of the individual worker's risk.

The notice under the OSHA Standard, including the Material Safety Data Sheet (MSDS) and other information provided to workers and customers under the Hazard Communication Standard explains what precautions should be taken and why. The information also helps the employees of both the manufacturers and the customers to take steps to improve safety in the work place.

The OSHA Hazard Communication Standard applicable to the manufacturing sector became effective last year, and industry supported the issuance of that rule. The present standard is in place and has an established enforcement mechanism. OSHA has under consideration and is expected to propose soon that the standard be extended beyond the manufacturing sector to include service and other industries. The expanded standard is expected to require hazard notification to all present employees throughout business and industry.

There has been no analysis or definitive study of the scientific and ethical basis for an individual worker notification program based on experimental animal data. Consequently, it is important that the term "study" in S. 79 be defined. If the term "study" as defined in S. 79 includes experimental animal studies, then separate valid scientific and ethical criteria for notification based on animal data need to be developed. We believe that the S. 638 is scientifically sound in confining its application to human studies. We urge that any proposed legislation be based on human data and studies.

In the meantime, it would be appropriate for the Congress to request the Congressional Office of Technology Assessment (OTA) or the National Academy of Sciences (NAS) to provide an evaluation of relevant scientific and ethical criteria for establishing an individual notification program based on experimental animal data. Such an evaluation would also provide Congress with an opportunity to review the expanded OSHA Hazard Communication Standard to be issued shortly.

Scientific Peer Review and the Separation of the Scientific Function from the Management Function

S. 638 sets out factors to be considered prior to promulgation of a notification program:

- the number of individuals and the extent of exposure, i.e. intensity, frequency and duration;

- the significance of the health effects;

- the medical benefits of providing individual notification. (We would add also the adverse consequences of such notifications.)

In order to achieve the objective of sound scientific evaluation of risk as a basis for a notification plan, there should be a provision for independent scientific peer review of the risk evaluation. Further, it is important that there be a clear distinction between the scientific function of risk assessment and the social function of risk management.

The 1983 National Academy of Sciences (NAS) landmark report on risk assessment (Risk Assessment in the Federal Government: Managing the Process) distinguished between the scientific risk assessment function and the risk management function:

- the scientific function is an unbiased evaluation of the data;

- the risk management function uses the scientific evaluation as a basis for applying social, as distinguished from scientific, criteria in determining the significance of the risk and what, if any, action is appropriate in light of the applicable statutory criteria or regulatory requirements.

The NAS study concluded that independent scientific review is the recognized way to ensure the scientific adequacy of a risk assessment as the basis for decision. Congress has recognized the importance of scientific peer review by creating, for example, the Science Advisory Board at EPA, the Science Advisory Panel under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and by providing for a scientific peer review panel under the Superfund Amendments and Reauthorization Act for studies by the Agency for Toxic Substances and Disease Registry at the Department of Health and Human Services (HHS).

S. 638 conforms to the NAS criteria: it provides for peer review -- by independent scientists -- of the scientific risk evaluation. The risk management function -- developing and implementing a notification program -- is vested in the Secretary of HHS who will use the scientific evaluation, ethical principles and other relevant societal factors in the determination.

S. 79 on the other hand, combines the two functions in a Risk Assessment Board made up of government employees. For the reasons set out by the NAS, AIHC urges that the makeup of the Board be changed into a separate panel of qualified independent scientists to review the adequacy of the science base to ensure an unbiased scientific risk evaluation.

The authority to make the risk management decisions -- who and how to notify -- vested in the Board by S. 79 should be separated from the scientific review. Since the determination to establish and implement an individual notification program raises many important, practical considerations, we urge that the risk management decisions be vested in the Secretary of HHS, (with appropriate authority to delegate). Certainly an essential and important aspect of this is that procedures and decisions should be governed by the normal requirements of due process, including notice and an opportunity for hearing and comment.

Practical Considerations

AIHC's comments focus on scientific and related ethical issues. We believe it is important to point out that in considering these bills and particularly S. 79, the Subcommittee should consider the potential for creating overlapping and conflicting administrative authority.

We have mentioned earlier the OSHA Hazard Communication Standard, and its expected expansion to all current employees throughout business and industry. Both bills potentially overlap this OSHA standard but S. 638 to a lesser extent.

Congress is aware also that the OSH Act provides that when issuing standards dealing with hazardous and toxic materials, OSHA shall prescribe as may be necessary not only for control of exposure but also for medical surveillance, the preparation of medical and exposure records and other provisions that OSHA finds to be necessary. This includes consideration of the matters covered in Section 9 of S. 79: medical removal and rate retention. Section 9 of S. 79 is thus duplicative and lacks the procedural and other legal requirements set forth in the OSH Act.

We have not attempted to make a detailed analysis of the overlap and duplication but we urge the Subcommittee to do so.

Conclusion

AIHC strongly urges that any individual worker notification plan should have a sound scientific and ethical basis and should be based on an evaluation of:

- the extent of exposure (frequency, duration and intensity);
- the significance of human risk;
- the possible medical benefits and adverse consequences of providing notice.

To achieve those objectives, a compulsory notification plan should be based on epidemiologic or other human studies. S. 79 should be modified to apply to epidemiologic and other human studies. The scientific evaluation should be based on all relevant data rather than the single study trigger provided in S. 79.

For experimental animal data, we have two comments. First, the OSHA Hazard Communication Standard provides a reasonable method of notification to workers of potential risks that may be used by a physician in assessing individual risk. When the OSHA Standard is expanded as expected beyond the manufacturing sector, it will provide effective notice to all current employees in industry and business. Second, we urge that Congress request OTA or NAS to provide an evaluation of relevant scientific and ethical criteria for an individual notification program based on experimental animal data. This will provide a sound basis for such a program.

To assure adequacy of the scientific basis for an individual notification program, a scientific panel of qualified independent scientists should be created to review the scientific risk assessment. We urge a modification of the function and the membership of the Risk Assessment Board in S. 79 to accommodate this approach.

A sound notification program should distinguish the functions of scientific risk assessment from the risk management. The important function of developing such a notification program should be vested in the Secretary of HHS (with appropriate authority to delegate). Because of the great importance of this matter, the procedure should assure due process, including notice and opportunity of hearing and comment.

We urge that any bill considered by the Subcommittee minimize overlapping and duplicative administrative functions.

AIHC does not have the capability to make an evaluation of the costs and other practical consequences associated with developing and implementing a sound individual worker notification plan. Our comments, therefore, have been confined to scientific and related considerations.

I would like now to introduce Dr. Reape. We would be glad to respond to your questions at the conclusion of his testimony.

Senator QUAYLE. Dr. Reape?

Dr. REAPE. Thank you, Senator.

I am the Director of Health Services for FMC Corporation, and my education and professional training are in epidemiology. I am here today in my capacity as the Chairman of the Epidemiology Committee of the American Industrial Health Council, and I appreciate the opportunity to be here and provide comment.

At the outset let me state that we urge this Committee to recognize the critical importance of the application of sound scientific principles in any occupational health-related program. We believe that S. 79 in its current form significantly fails to identify and to include accepted scientific principles.

At the same time, we believe that S. 638—your legislation, Senator Quayle—much more closely follows scientific consensus. It would lead to the development of the sort of information which may assist those of us in the occupational health field to fulfill our most important objective, and that is the prevention of disease and the extension of life.

Specifically, let me state the following conclusions, amplified in greater detail in my written statement.

First, for properly evaluating chronic health hazards, epidemiology studies are necessary to provide clear evidence of cause and effect relationships between exposure and health risks.

Second, all available epidemiology studies and other human data relevant to a scientific determination whether there is exposure and health effect should be included in such an assessment. This includes both positive and negative epidemiology studies.

Third, epidemiologic information used in such an overall determination of causality or high risk of individual populations should be evaluated on the basis of the principles adopted by the Advisory Committee of the Surgeon General of the Public Health Service when reviewing the issue between smoking and health. These include: strength of the association or the magnitude of the effect; consistency across multiple studies; specificity of the health effects; the temporal relationship in time—that is, the relationship between exposure and health effects—and the coherence of the evidence in terms of all available scientific evidence; additionally, the biologic gradient—that is, that there be increasing effect with increasing intensity and time of exposure—and the biologic plausibility.

There are additional scientific criteria commonly accepted and addressed in the NIOSH study which we have heard earlier, to determine the weight or significance to give each individual epidemiologic study to be included in such an assessment. These include: the design of the study; the definition of the cohort; the quantification of exposure; the mortality and morbidity ascertainment and validation; the identification of compounding factors and alternative causes of the endpoint being observed, and the statistical analyses.

In short, Mr. Chairman, S. 79 has addressed two scientific criteria—that of statistical significance and that broadly-established scientific criteria should be applied.

But these references are not enough when there are specific, agreed-upon principles for which there is broad consensus in the scientific community. These criteria, which are specifically referred to here in my verbal testimony and in more detail in my written testimony, need to be incorporated into any notification effort.

We are pleased to see that S. 638 would provide for consideration of many of the relevant scientific factors for sound scientific evaluation of risk, and we strongly support the provision in the bill for peer review.

At your pleasure, I would be pleased to specifically review those scientifically-accepted criteria in more detail to which I have referred now, or at a later point in testimony.

Thank you very much.

Senator **Quayle**. Thank you very much, Dr. Reape.

Dr. Burger, in your statement, you were quite supportive of the notification framework described in the report of the NIOSH Board of Scientific Counselors on the individual worker notification. I also looked at that report, and as a matter of fact tried to focus S. 638 around some of those recommendations.

Do you think that we have done a fairly good job of incorporating those recommendations into legislative language that will set up the appropriate mechanism to determine when we should notify, what notification should be based upon, and how and who we go about notifying?

I wonder if you might just comment on the NIOSH Board of Scientific Counselor's recommendations and how we have incorporated those recommendations into S. 638.

Dr. **Burger**. I appreciate your question. I think the short answer is yes, I think you have gone considerable distance in that direction.

If I recall, your proposal also includes the imposition of a type of administrative process—a filter, in a sense—before notification in fact becomes a certified notification, or an official notification.

Senator **Quayle**. That is correct.

Dr. **Burger**. I think the spirit of your proposal in the sense of incorporating a mechanism for judging the scientific quality of the material leading to a notification is absolutely correct and in fact does mirror the recommendations of the Board of Scientific Counselors.

The imposition of an administrative process, I must say candidly, bothers me a little bit, because I think that may be more of an encumbrance than a productive mechanism in this regard.

In short, I think I would favor a mechanism that you and everyone else will have confidence in in judging the scientific material, but I would stop short of inserting an administrative-type process of comment and notification and so forth that I think you have also included in that.

Senator **Quayle**. Would have the comment on the administrative process?

Dr. **Burger**. I would establish an advisory review body, a standing body, in whom the country could have confidence, to review the scientific material that would or would not lead to notification, and I would place my confidence in them.

Senator **Quayle**. And not have any review of that.

Dr. **Burger**. That is right.

Senator QUAYLE. Okay. We will take note of that. Our interest is in having the Secretary look at this, since he has the overall responsibility. We would like to at least bring him in, but I understand perfectly clearly what you are saying.

You also focused on the need for sound scientific data in making these notification decisions. I wonder if you might just comment specifically on the quality of the science in S. 79 and what that data would be like and particularly the kind of data that they would rely upon to give the notification?

Dr. BURGER. If I understand the proposal in S. 79 correctly—and I think I do—essentially any piece of information called scientific information, any study, could in fact trigger a process which would put the proposed review board into being and ask them to review it.

In effect, I think the likelihood is that any piece of datum, any scientific information, a study from any source, could in practice lead to notification, the board's review notwithstanding under S. 79. That is a troublesome matter, I think.

The area that I focused on concerned data from human studies, not from all sources but from human studies. That is point number one. There needs to be established a set of criteria or guidelines for judging those human studies and a review body which will in fact perform the review.

One ought to carefully hew to those two things, I think, in order to assure oneself that in fact the notification is triggered appropriately and is followed through appropriately.

There are two parts I would propose to the review process. One conforms to what is usually considered the business of peer review in a traditional sense for scientific data, and that concerns for the most part the validity of the data. Do the data reported in fact resemble or approach the truth of the scientific matter. The terms of this aspect of the review include consideration of the quality of the design of the experiments, the analysis of the results, and a determination as to whether they do or do not seem to square with other scientific results culled from other experimenters independently. Can they be confirmed independently by other experimenters, and so forth. It is a series of steps that traditionally scientists observe when trying to judge the validity of data. So that is one thing, I think.

The second thing has to do with the interpretation of those data for human health; what do they mean? Do the reported findings, if they are positive, suggest a phenomenon that in fact is transient or adaptive, or is it something that is pathological, that is serious, that is irreversible? And what seems, in the scale of medical seriousness, to be the appropriate interpretation of those findings for human health and disease?

Those two things, I think, are important, and they are in fact embodied, I think, in the guidelines that were prepared for NIOSH for human studies. I think they should be observed, in every case. I am not sure that they are going to be at all observed without special attention They are not spelled out at all in S. 79.

Senator QUAYLE. Dr. Reape, do you have any comments on the quality of data for making notification that S. 79 relies upon?

Dr. **Reape**. It is the absence of criteria in S. 79 which concerns us most. If there is reliance on human data or clinical data and attention to that sound science and if you have a very appropriate Board with all the scientific disciplines represented, then you may have an accurate assessment of risk and an appropriate assessment of what types of interventions may help those who are at such high risk.

But it is the absence of these specific requirements. If S. 79 contain such items as that they look at the strength of association and the magnitude of effect and the other items which I included in my testimony, I think S. 79 will have been brought a long way towards addressing a lot of the commonly accepted principles that scientists used in making a cause-and-effect association based on human data.

The animal data is extremely important in understanding the coherence of the evidence and in raising questions and hypotheses. But if S. 79 does not specifically note that epidemiology studies are necessary to identify high-risk populations, then we will be at risk of making a lot of false positive judgments on individuals to be at high risk, and that severely concerns us, Senator.

Senator **Quayle**. Okay.

Dr. Burger, from an ethical standpoint, what do you think of the notification that will actually be generated under S. 79?

Dr. **Burger**. Well, I hope I have hinted at that, at least, in my testimony. I am terribly anxious about it, in candor.

I spoke, I believe, of the possibility of false positives and false negatives. False negatives are as much of a reality as false positives in findings, but they will presumably be lessened in number by the very notification process itself. That is, the momentum of the process will in fact tend to diminish the importance of false negatives, but it will raise more prominently the problem of false positives.

The ethical problem associated with false positives is potentially substantial, and I urge this body and the Congress to take that matter very seriously. The possibility of raising false concerns of a medical sort among a population of people has ethical and legal and economic and medical considerations, which led me to raise the issue of one should be careful not to do harm.

Senator **Quayle**. And in being careful not to do harm and making sure that we do not raise false concerns, peer review would address the validity of the data, and the interpretation of that data. I would presume you would feel that those two guiding principles would answer some of the ethical concerns on notification. Am I correct in drawing that conclusion?

Dr. **Burger**. If addressed appropriately by a body of persons who were technically expert and recognized as such, I think the process would go far toward reducing the probability of bringing false positives into this picture.

Senator **Quayle**. So the key is peer review and the flexibility, I presume, that that peer review has.

Dr. **Burger**. Absolutely.

Senator **Quayle**. So therefore you would like to place the data before the peer review groups and ask them to give you the answers.

Dr. **BURGER**. I agree with that entirely.

Senator **QUAYLE**. And then you would stop it right there. That would be the conclusion, and then we add one thing to that?

Dr. **BURGER**. That is right. I would pass that recommendation on to the Secretary as an advisory recommendation, but I would not lay on an additional administrative process on top of that.

Senator **QUAYLE**. Okay.

Dr. Higginson, let me ask you a couple of questions. I appreciate you being here.

Do you agree with the intent of S. 79, Senator Metzenbaum's bill, just the basic intent of that bill?

Dr. **HIGGINSON**. If the intent is to prevent premature death or morbidity from disease arising in the workplace, I do.

Senator **QUAYLE**. How effective do you think the bill will be to achieving that result?

Dr. **HIGGINSON**. I have a belief in selective notification under prescribed conditions. These have been extensively studied by several bodies, NIOSH and others, and many scientists. I have serious reservation regarding what appears to be blanket notification for every known physical, biological, chemical in the universe. I also believe that the logistic support proposed to carry out the program are inadequate. They probably could be more effectively directed toward what I would regard as the "new-fashioned" methodologies rather than old-fashioned approaches.

Senator **QUAYLE**. Would you agree that the conversation we have had with Dr. Burger on the peer review process that would be established and the interpretation of the scientific data is key to answering some of the concerns that you have? Are we going in the right direction from your viewpoint?

Dr. **HIGGINSON**. Sir, if you have a situation of defined, clearcut risk, and clear guidelines for notification, a peer review board may be able to do the job. But the more you widen the scope, the more you require that the board should look at the primary data. In this case you are initiating a very considerable scientific bureaucracy which will overlap many established bodies.

Senator **QUAYLE**. Dr. Higginson, in the late 1950s, you were credited with making what many felt at the time was an outstanding statement, that 70 to 80 percent of cancers were environmental.

I wonder if you might be able to elaborate on that and to bring that into the context of the 1980s and as we go to the 1990s.

Dr. **HIGGINSON**. I have had to live with misquotations for 30 years.

Senator **QUAYLE**. Oh, misquotations?

Dr. **HIGGINSON**. Yes.

I basically said that 80-odd percent of cancers had an environmental component, and therefore were theoretically preventable. Unfortunately, I have been quoted as saying 80 percent of cancers were 100 percent due to the environment and 100 percent preventable.

I am afraid that in our early days we were rather simplistic. We considered most cancers were due to obvious exogenous factors like chemicals. That is what we started to examine the impact of, industrial pollution. As time went on, we realized the causes of human cancer were part of a much wider universe, including not only cultural habits, but diet and other factors. These are all part of the environment. But they are very pertinent now, when you consider any group in the population. There are enormous variations in this country between various segments of the community and between various occupations.

It is highly desirable that you know the facts, why those variations exist and how you can best target and prioritize them. In that sense, therefore, I believe prevention is possible when you know the causes, but today many situations we believe are best studied through "molecular epidemiology" and that prevention may through intervention may be more expective.

Senator **Quayle**. Dr. Higginson, at the February 24th hearing of this Subcommittee, many of the witnesses testified that the passage of S. 79 would significantly reduce health care costs. They argued that if we established, as you talked about, blanket notification, that health care costs would dramatically decrease.

Do you agree with that assessment and that conclusion?

Dr. **Higginson**. There have been a number of bodies that have looked at the reduction of health costs. There are situations where people have been exposed, say, in a coal mine, to silicosis or pneumoconiosis, to cotton dust, et cetera, where removing them will reduce premature mortality and morbidity. That is standard procedure; you get people out of harm, and you reduce the immediate costs.

If, however, you are talking about total costs of the American population over the next 50 years, the longer you keep people alive, the greater the costs are. [Laughter.]

Senator **Quayle**. Whoops.

Dr. **Higginson**. I do not think cost has anything to do with it. There can only be a humanitarian approach.

Senator **Quayle**. Okay. Dr. Burger and Dr. Reape, would you comment on the idea that if we in fact would pass this bill that health care costs would go down? That was sort of the conclusion, that was stated.

Dr. **Burger**. I am afraid I am terribly skeptical. I think you should hold those who have made those statements to the fire to the extent that ten years from now, we should find out whether or not those predictions were borne out. My bet with you is that there will be no measurable change in health care costs associated with the passage of this bill. Its intent is otherwise, and I respect that. But I think it is wrong to suggest that expenditures for health care are a surrogate for other desirable features in this case.

I think the short answer is no, they will not be measurably reduced.

Senator **Quayle**. Thank you.

Dr. Reape?

Dr. **Reape**. Well, I do not have an expertise, really, to judge how health care costs would come down. I would always assume that prevention of disease would not only bring costs down, but then there are non-economic benefits.

The primary preventive tool that any legislation should seek in this area of occupational health is the reduction in exposure, or the elimination in exposure. That is how you prevent disease primarily in occupational health, as Dr. Higginson alluded to. So if you find out somebody is at risk because they are exposed to coal dust, you remove them from exposure.

Informing somebody ten years after they have been exposed and then subjecting them to periodic medical surveillance, the amount of actual clinical benefit and reduction in suffering such an individual would receive is limited to a relatively few diseases and so would not be broad in terms of its ultimate impact, whereas science seeks and medicine seeks to cause intervention so that we can diagnose disease early and hopefully impact a lengthening of lifespan. Unfortunately, with a disease like lung cancer, early diagnosis does not extend life. But in the future, hopefully, such breakthroughs will come through.

But I am saying the long and short of it is the primary prevention of reduction in exposure which is achieved, basically, through OSHA and Hazard Communication and through our ongoing occupational health programs and epidemiology and tox programs in industry is how we are going to truly prevent occupational disease.

Senator QUAYLE. Well, yes, that gets back to the point. If you take that idea that in reducing health care costs you are going to improve one's health, the way to improve one's health in this whole area is on the standards that we establish in the workplace. For example, to try to lessen the risks to employees we could establish how much coal dust you are going to allow; if coal dust is the problem, then let us try to create an environment where you do not have that.

I wonder, Dr. Higginson, if you might just comment on the techniques of intervening during the latent period of such chronic diseases as cancer and success of such intervention.

Dr. HIGGINSON. I wish to divide my answer into two. First, today, the only industrial cancer that I know that we may be able to interfere in is bladder cancer for early diagnosis. For cancers, such as breast and cervix, where the occupational risk is very limited, we can also have some impact through early diagnosis. The impact is relatively modest in the first case, and in my opinion, in those cases they should apply to everybody.

Lung cancer, which is a cancer of great concern in the workplace—people have studied it extensively—can be reduced by removing individuals from the risk—but in terms of early diagnosis, all studies have been useless. I believe that if the people who wish to emphasize that intervention as suggested is effective, such intervention techniques should be widely bruited abroad and applied to the total population and not be confined to a limited group. I should say that all smokers should have the advantage, for example, of such techniques

On the other hand, there is no doubt that in terms of cancer research for the next ten years of this century, we will be increasingly trying to interfer in the cancer process, early, before the cancer develops, i.e. by dropping a spanner in the works. Unfortunately, at the present time, research has not developed to a level where one could make any strong recommendations except to do more research, but that is not the intent here. But that is a way, I think, we are going to go, because I think we really know the big risks today—there will be new ones, a few. Our worries relate, rather, to the smaller risks, which cause a great deal of controversy as to whether they really cause a problem.

Where you have a real risk, I do not think we have any problem. My belief is that intervention at the moment will, in 10 or 15 years, be the wave of the future—in a difference sense from that implied through notification.

[Additional information subsequently supplied for the record by Dr. Higginson follows:]

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March 16, 1987

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Senator Daniel Quayle
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Dear Senator Quayle:

Further to the hearing March 9, regarding Bill S79 and S638, I failed to make the following points due to time limitations:

1. S79 basically attempts to set up a large bureaucratic organization for notification of potential risks without first determining the facts. Such data are essential to the selective targeting and prioritization of problems and the evaluation of the probable effectiveness of the proposed procedures.

   S638 on the other hand, proposes that such information should first be generated and analyzed. Further, that notification should be selective.

2. There are marked variations in health in the U.S., both within the workplace and between communities. Apart from a number of clearly recognized diseases and hazards, e.g., mesothelioma, byssinosis, etc., the extent and causes of such variations have not been adequately analyzed in the country as a whole.

   I have checked with the National Academy of Science and their report on the collection of data in workplace diseases in the U.S. will become available this summer. I understand that the situation is very unsatisfactory (contact Dr. Earl Pollack, NAS). I suspect that this report will have significant implications for both Bills.

   To rely only on a single statistically positive epidemiological study or mutagenic test to identify a significant variation, is not scientifically acceptable and may only confuse the issues. Such a simplified approach would not reflect modern epidemiological concepts.

3. The following examples illustrate the complexities of health variations in the workplace: (a) Data available on occupation and mortality from the United Kingdom indicate that nearly 90% of cancer variations in the workplace and between communities are due to factors (largely socioeconomic) other than direct workplace exposures. (b) In this country, blacks have twice the cancer morbidity of individuals of Japanese extraction. These differences are reflected in the workplace. (c) Some large scale industries in the U.S., with stable work forces, have about 80-90% of the cancer risk of the general population. This is not a healthy worker effect. However, it implies that other less controlled workplaces, such as "Mom and Pop" shops, may have considerably worse experiences, yet relatively little is known about such groups.

Thus a notification system directed only to large scale industries as being those most capable of implementing such procedures, may be ineffective, in terms of prevention, as such industries probably represent only a fraction of the health variations. Further, the greater burden of ill health in less controlled workplaces and communities will be ignored. Yet it is in these latter that safety measures are at present least likely to be adequately developed or general health measures applied.

4. In attempting to obtain the background information necessary for reducing the burden of work related disease and expediting the evaluation of future actions, the following would appear to be necessary.

(a) Coding of occupation on Death Certificates. As a preliminary step, coding of occupation on death certificates in all states would be most helpful. The major occupation is already on the certificates but is not coded in all states. An even smaller number of states make their coded data available to the National Center for Health Statistics (NCHS). Availability of such data would provide at least a baseline for documenting and analyzing occupational disease variations in the U.S. as is now done in England and Canada.

The NCHS appropriation expires in 1988, but the Center has applied for further partial funding. This study should be extended to the whole country. Such coding, I am informed, would cost approximately $1.3 million.

R. W. Wilson, Director, Division of Epidemiology and Health Promotion, National Center of Health Statistics, (301/436-7032), will be happy to provide further information on this problem.

Additional useful information will become available from:

(b) The NHANES III starting in 1988.

(c) The Health Interview study for 1988, sponsored by NHS/BLS/NIOSH.

(d) The Maternal and Infant study.

In my opinion S638 would be improved by spelling out such needs in detail. Such information would clearly enrich both Bills.

5. Research Needs. In relation to the objectives of the Bills, research is clearly necessary (a) to accurately document exposures; and (b) evaluate the effectiveness of intervention in chronic diseases.

(a) Exposures. The present Bill seems to rely on old-fashioned approaches to determine exposures. Newer techniques are becoming available for determining more accurately, exposures to chemical carcinogens and other factors. These are being investigated by the modern techniques used as "molecular epidemiology". Such approaches are ignored in the Bill and yet they are essential if any early notification system is to prove successful and practical.

(b) Intervention. As apart from removal of individuals from obviously hazardous situations, there is little that can be done for most chronic diseases, such as cancer. Medical science can intervene successfully in a few rare exceptions, e.g., carcinoma of the cervix or breast. However, prevention through intervention in mechanisms is seen as offering the best approach to the control of cancer in the future. In the meantime, to push for notification of disease potential based on poorly understood minor physiological variations from the norm may cause harm and provide no benefit to the individual.

Moreover, where effective and practical methods of intervening in chronic disease are available, they should be available to members of all high risk communities and not a selected segment.

6. I personally believe that the health of a community should be considered as a whole, and not be approached through a segmented or piecemeal approach, although there are clearly defined exceptions where individual groups are at unusual risk.

If necessary, I would be happy to discuss these points with you or the committee staff and elaborate.

Sincerely yours,

John Higginson, M.D.
Senior Fellow

JH:my

Senator QUAYLE. Thank you.

Gentlemen, thank you very much.

We are delighted to have Senator Humphrey join us. I am just about prepared to dismiss this first panel, Senator Humphrey.

Senator HUMPHREY. I think that is a good idea.

Senator QUAYLE. Okay. We will keep the record open for any opening statements and also any questions that members of this Subcommittee might like to submit to this panel.

Thank you very, very much for your testimony. It has been most enjoyable and enlightening, and we will be looking forward to working with you as this legislation progresses.

Thank you very much.

Dr. BURGER. Thank you, Senator.

Senator QUAYLE. Next will be James Patterson, Wallace Parker, Peter Ruane, and Eugene Humphrey.

Let us go ahead and proceed. We took an hour with that last panel. I was planning on concluding this by noon, and I have got three other panels, so I am going to institute the five-minute rule. I think you have all been advised that we would like to keep your comments to five minutes, and to help me along, I have got an electronic device up here, green and red. You all know what that means. Green means "Talk," and red means "Stop." It is pretty simple. So when the red comes on, stop within a reasonable period of time, and I might politely remind you if you go beyond that.

Our first witness is Eugene Humphrey, who is President of Humphrey Chemical Company, on behalf of the Synthetic Organic Chemical Manufacturers Association.

Mr. Humphrey, welcome, and proceed.

STATEMENTS OF EUGENE HUMPHREY, PRESIDENT, HUMPHREY CHEMICAL CO., ON BEHALF OF SYNTHETIC ORGANIC CHEMICAL MANUFACTURERS ASSOCIATION, INC.; JAMES F. PATTERSON, PRESIDENT, OHIO FARM BUREAU, ON BEHALF OF AMERICAN FARM BUREAU FEDERATION; WALLACE PARKER, CHAIRMAN, HEALTH AND SAFETY COMMITTEE, ASSOCIATED GENERAL CONTRACTORS OF AMERICA, AND DR. PETER RUANE, CHAIRMAN AND TREASURER, SMALL BUSINESS COUNCIL

Mr. HUMPHREY. Thank you, Senator.

Mr. Chairman and members of the Subcommittee, I am Eugene B. Humphrey, President of the Humphrey Chemical Company and appearing here today on behalf of the Synthetic Organic Chemical Manufacturers Association, of which SOCMA is the acronym. I appreciate the opportunity to give this statement.

SOCMA is a nonprofit trade association with approximately 140 members. Many of SOCMA's member firms are small businesses with annual organic chemical sales below $50 million. Humphrey Chemical, for example, has approximately 50 employees and a total annual sales of approximately $10 million.

SOCMA's members, both large and small, endorse the right of an employee to be informed of exposure to hazardous substances. However, SOCMA believes that S. 79 may cause an increase in the cost of or the outright elimination of health, life and worker compensation insurance available to employers with workers identified in at-risk categories.

Humphrey Chemical and SOCMA's other members, generally provide health benefits to their employees. The costs of premiums for health coverage have increased markedly—in Humphrey's case, about 25 percent over the last year, and the cost of workmen's compensation insurance has increased even more dramatically.

At present, the insurance industry generally does not question SOCMA's small member companies about the potential hazards associated with the chemicals in their workplaces. However, insurance company testimony has indicated that after enactment of S. 79, the small businesses in the chemical industry with employees designated as at-risk would lose the benefits of pooling into a large population group. Inevitably, higher premiums would result, because the experience base in a small company may be of insufficient size to be an adequate predictor and because notification likely would lead to an increase in health claims, whether justified or not.

Further increases in insurance may force small companies with limited resources to reduce other employee benefits. SOCMA also believes that S. 79 may cause spurious workers' compensation and product liability actions, based on limited or unsubstantiated data by employees designated as at-risk, these would impose significant unwarranted costs on the chemical industry and exacerbate the current difficulties in obtaining workers' compensation and liability insurance.

The litigation resulting from S. 79 in many cases would be without merit. Senator Quayle, your bill, S. 638, recognizes this issue and includes provisions designed to limit the impact on workers' compensation proceedings.

Finally, S. 79 as currently drafted may impose medical surveillance on employers in situations where it is not warranted because its costs in terms of expense to the employers and the anxiety to employees would not be offset by public health benefits. A SOCMA survey indicates companies with medical surveillance programs spend an average of about $175 per employee. It is likely that the sophisticated testing required by S. 79 would be even more disruptive.

These small business concerns are particularly acute in the context of S. 79, because substantial over-notification to employees not actually at-risk could occur.

In view of the significant implications for both employers and employees, notification should be based on a sound scientific review of all available data. Your bill, S. 638, is a useful first step in this regard.

However, SOCMA remains concerned that any legislation which proceeds to identify populations at risk will significantly affect the ability of small companies to obtain affordable insurance benefits.

SOCMA supports the Hazard Communication Standard which establishes an appropriate mechanism for companies to provide information to employees about potential hazards in the workplace. OSHA will soon be expanding the standard to non-manufacturing sectors. Through the right-to-know provisions of the Superfund amendments, all individuals including former employees are entitled to information made available by the Hazard Communication Standard.

These measures, as well as generic standards for medical surveillance and monitoring, which we understand are now under consideration at OSHA, are appropriate vehicles for implementing an informational and medical surveillance program without provoking a crisis in the small business community.

Thank you for providing us this opportunity to appear.

Senator QUAYLE. Thank you very much, Mr. Humphrey.

[The prepared statement of Mr. Humphrey, with attachments, follows:]

WRITTEN STATEMENT

OF

THE SYNTHETIC ORGANIC CHEMICAL MANUFACTURERS ASSOCIATION

BEFORE THE

SUBCOMMITTEE ON LABOR

COMMITTEE ON LABOR AND HUMAN RESOURCES

UNITED STATES SENATE

ON

S. 79,
THE HIGH RISK
OCCUPATIONAL DISEASE NOTIFICATION
AND PREVENTION ACT
OF 1987

March 5, 1987

The Synthetic Organic Chemical Manufacturers Association ("SOCMA") appreciates this opportunity to provide testimony for the record on S. 79, the High Risk Occupational Disease Notification and Prevention Act of 1987. SOCMA is a non-profit trade association with approximately 140 members. Many of SOCMA's member firms are small businesses with annual organic chemical sales below $50 million.[1/] SOCMA's members produce a wide variety of synthetic organic chemical products which are essential to virtually every other major American industry and are responsible for much of the innovation in the industry today.

SOCMA strongly recognizes the right of an employee to be informed of his exposure to hazardous substances. This is a basic right of the employee and the responsibility of the employer. For example, SOCMA supported the development of the OSHA hazard communication standard. Pursuant to the hazard communication standard, SOCMA's member companies provide notification to employees about the risks associated with

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1/ SOCMA's significant small business membership is representative of the organic chemical industry as a whole. The Small Business Administration's Data Base shows that of firms in the industrial organic chemicals industry, SIC Code 2869, 85 percent employ fewer than 50 persons.

exposure to potentially hazardous substances through training, labeling, and material safety data sheets.

However, SOCMA is concerned that the legislation as currently drafted may have significant adverse impacts on its member companies, particularly the small business segment, and on their employees. In particular, SOCMA believes that S. 79 may: (1) cause an increase in the cost of, or the outright elimination of, health, life, and worker compensation insurance available to employers with workers identified in "at risk" categories; (2) increase employer's exposure to liability claims based on limited or unsubstantiated data, and therefore affect the cost and availability of workers' compensation and liability insurance; and (3) impose significant costs of medical surveillance in circumstances where it is unwarranted. These impacts could cause small businesses to lose their ability to attract employees and to price products competitively with larger companies. Some small businesses may be forced to alter their product lines or to close altogether.

These concerns of small business are particularly acute in the context of S. 79 because substantial over-notification to employees not actually "at risk" could occur. The proposed risk assessment board to be established within the Department of Health and Human Services would not be required to adhere to rigorous development of scientifically-defensible conclusions. Over-notification could impose unwarranted anxiety and other impacts on the notified employees and unwarranted burdens on the employer, without any offsetting benefit to public health.

I. OVER-NOTIFICATION TO EMPLOYEES NOT ACTUALLY AT SIGNIFICANT RISK

S. 79 as currently drafted likely would result in over-notification to employees not actually facing a significant increased risk. Under the broad notification criteria in S. 79, many employees would be designated as at risk who would otherwise be excluded if the determination were based upon sound science and principles associated with a well-conducted risk evaluation.

Specifically, Section 3(7) of S. 79 defines an "occupational health hazard" as a substance "for which there is statistically significant evidence (based on at least one study conducted in accordance with established scientific principles) that acute or chronic health effects may occur in exposed employees." This definition is based on the OSHA hazard communication standard, 29 C.F.R. § 1910.1200(c), which was designed to be a "broad approach" that would require employers to "evaluate and communicate information concerning all the potential hazards associated with a chemical." 51 Fed. Reg. 53280, 53295-96 (Nov. 25, 1983). Although the hazard communication standard's approach may be appropriate for early warning purposes and for triggering on-site training, labeling and material safety data sheets to address normal and emergency situations, it is not appropriate for triggering notification to employees that an actual risk of disease is present. Such notification, in view of its consequences for both employers and employees, is appropriate only where a balanced review of all of the scientific evidence indicates that a significant risk is present. Further, Section 4(b)(3)(C) mandates notification of a minimum of 100,000 employees per year and states that the risk assessment board must undertake "every reasonable effort" to notify 300,000 employees per year. Application of this arbitrary threshold requirement would not reflect a reasoned consideration of the scientific evidence regarding the existence of an actual, significant risk.

The designation of a class of employees as an "at risk" category may thus stimulate an insurance industry expectation that higher health care costs and mortality rates would be associated with those employees. It also may cause an increase in spurious workers' compensation and liability claims by employees who are falsely led to believe that their condition resulted from occupational exposure, as well as needless anxiety among such employees. SOCMA believes that any notification should be based on sound science and have a demonstrable benefit. In addition, to avoid unwarranted alarm any notification should include as a component a realistic evaluation of the employees exposure, of the likelihood of actual harm, and of the degree of excess exposure that is present.

II. IMPACTS OF S. 79 ON CHEMICAL COMPANIES AND THEIR EMPLOYEES

The substantial over-notification that would result from S. 79 would have significant impacts for SOCMA's members in terms of: (1) the availability and cost of health and life insurance for employees; (2) an increase in spurious workers' compensation and liability claims and associated insurance availability problems; and (3) imposition of the substantial cost of medical surveillance in situations where it is not warranted. These impacts would be particularly burdensome for SOCMA's small business members.

A. Availability and Cost of Health and Life Insurance

The majority of SOCMA's member companies provide insurance benefits to employees, typically in the form of health insurance and life insurance. These insurance benefits are a essential component of the overall compensation package offered by employers. Over the past several years, insurance premiums have significantly increased, and in some cases individuals identified as being in certain "high risk" categories have been denied insurance. SOCMA is concerned that S. 79 could have the unintended impact of significantly increasing the cost of, or eliminating the availability of the insurance programs offered to employees. These impacts may be particularly acute for small businesses, who do not have the capacity to self-insure and who rely on their insurance programs as an important aspect of their compensation package to compete with larger companies for capable employees.

A recent survey of SOCMA's membership revealed that all of the member companies responding currently provide health and life insurance to their employees.[2] Of these companies, about 70 percent do not self-insure, but rather turn to the insurance industry for reasonable, affordable benefit packages.[3] Insurance premiums for these companies have increased up to 100 percent in the past five years; the median increase was [illegible] percent.

SOCMA believes it likely that enactment of S. 79 would result in additional significant increases in the cost of insurance, particularly for small businesses, and in some circumstances may result in elimination of insurance availability. At the present, the insurance industry generally does not question SOCMA's small member companies about the potential hazards associated with chemicals in their workplaces. As a general rule, insurance companies have performed actuarial risk analysis by first pooling small groups

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2/ A broad-based survey of the U.S. workforce by the U.S. Chamber of Commerce recently determined that 86 percent of all companies provided health insurance benefits to employees. Research Center, Economic Policy Division, U.S. Chamber of Commerce, Employee Benefits 1985, at p. 18.

3/ The companies who do not self-insure generally are small businesses who do not have sufficient employees to diversify risks or are located in states prohibiting self-insurance. Among the small businesses, over 80 percent turn to insurance carriers for coverage. The survey also indicated that self-insurance is prohibited in New Jersey, Texas, and West Virginia.

with others to form a larger population. The risk is then calculated for the entire population group based on community ratings, experience ratings or a combination. The higher the expected health care costs, the higher the premiums.[4]

If S. 79 is enacted, it is likely that the insurance industry would separate out specific companies from the general pool based on the requirements for employee notification. The testimony of the Blue Cross and Blue Shield Association before the 99th Congress is instructive:

> In dealing with small insured groups Blue Cross and Blue Shield Plans consider them as part of a pool and calculate a small group premium based upon spreading the risk more broadly across the composite, "super group." This is done in an effort to set affordable premium rates in a part of the market where, due to small group size, changes in the health status of few groups members can have a huge impact on the financial risk a small group presents. In small group pooling or community rated situations, which generally involve employers of 100 or fewer persons, the higher risk of health care costs presented by "notified" employees would thus be spread across a larger population. If S. 2050's mandated benefits were to create significant costs in this already difficult to insure segment of the market, competitive forces could pressure Blue Cross and Blue Shield Plans to discontinue pooling and instead rate each small group according to the risk which it alone presents. This would result from healthier small groups refusing to"subsidize" the

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4/ See Committee on Risk Classification, American Academy of Archives, "Risk Classification Statement of Principles," June 1980, Exhibit 1.

> cost of S. 2050's special benefits for persons in other small groups. If this were to happen, the the smaller the insured group the greater its premium increase would be, due to the inclusion of "notified" employees. In some cases, small employers might find health insurance altogether unaffordable.

Statement of the Blue Cross and Blue Shield Association on S. 2050, May 15, 1986, Exhibit 2, at p. 8.

After enactment of S. 79, the small businesses in the chemical industry with employees designated as "at risk" thus would lose the benefits of pooling into a large population group. SOCMA believes that notification would be taken into account by insurance companies and would inevitably lead to higher premiums, because the experience base in a small company may be of an insufficient size to be an adequate predictor and because notification likely would lead to an increase in health claims, whether justified or not.

SOCMA also is concerned about whether insurance would continue to be available to notified employees at any price. Numerous insurance companies have already moved away from providing health benefits to population groups that are determined to be in high risk categories. Although dramatic, the elimination of insurance availability for individuals , exposed to the Acquired Immune Deficiency Syndrome (AIDS) virus led the District of Columbia to enact anti-discriminatory legislation.[5] Similarly, designation of certain employees as "at risk" by a governmental entity may have the effect of eliminating the availability of insurance to cover such employees.

B. Effect on Workers' Compensation and Liability Insurance

SOCMA believes that S. 79 may trigger spurious workers' compensation and product liability actions by employees designated as "at risk," thus imposing significant unwarranted costs on the chemical industry and exacerbating the current difficulties in obtaining workers' compensation and liability insurance. The ability of companies to obtain such insurance at reasonable cost is an essential precondition to the conduct of business in the chemical industry.

The litigation against chemical companies resulting from S. 79 in many cases would be without merit but nonetheless would require significant expenditures to defend. Much of the litigation likely would involve employees with diseases from causes other than occupational exposure, employees who sue for fear of contracting a disease, or employees who sue because of a falsely perceived increased likelihood of contracting a disease. In addition, notification could inappropriately suggest liability in workers' compensation actions. As discussed above, these effects are exacerbated because S. 79

5/ D.C. Law 6-132, Exhibit 3.

would result in substantial over-notification to employees who, in actuality, are not at increased risk. Consequently, notified employees may attribute to their occupational exposures conditions actually based in other causes.

A similar response to publicity about a potential risk has been observed in other contexts. For example, after polybrominated biphenyls (PBB) were introduced into the food chain in Michigan in 1983, a number of spurious health effects claims were observed. A study of 23 farmers with disabling health complaints that they believed to be associated with PBB, which included a systematic evaluation of possible adverse effects, concluded that the patients "were not found to have objective evidence of deleterious effects at this time" and that "[t]here was no relationship between PBB levels and physical or laboratory abnormalities." Stross, et al., "Human Health Effects of Exposure to Polybrominated Biphenyls," 58 Toxicology and Applied Pharmacology 145 (1981), Exhibit 4. Therefore, any notification must be carefully based on sound science, be expressed in terms understandable to the individual notified, and be designed to serve a demonstrable medical benefit in order to avoid unwarranted impacts on the chemical industry.

Even without enactment of S. 79, workers' compensation and liability insurance has become a significant issue. Alleviation of the current liability insurance crisis was recently identified as the highest priority issue of the sixty final recommendations of the White House Conference on Small Business during 1986,[6] and the limited availability of liability insurance to physicians and municipal governments has been well documented. Several of our members have informed us of their current difficulties in obtaining such insurance. For example, Sterling Chemical Company recently completed a plant purchase in Texas City, Texas, in which one of the major issues was the placement of workers compensation and liability insurance. Although a number of major insurance companies were asked to provide coverage, only one company was willing to provide a quotation. The insurance that was obtained was at a very high premium and imposed restrictive policy terms and conditions. In response, some chemical companies have been forced to pool together to form captive insurance companies to provide coverage,[7] and a number of states have implemented revisions to their workers' compensation programs to restrict benefits in order to continue to attract industry.[8] S. 79

6/ The White House Conference on Small Business, A Report to the President of the United States, Nov. 1986, Exhibit 5, at 21-22 (stating that "the liability insurance crisis in the United States has not only become a life and death sentence to many small businesses, but also is changing adversely our way of life . . .").

7/ "Chemicals Go to Captives for Coverage," Chemical Week, Feb. 11, 1987, at 68, Exhibit 6.

8/ See, e.g., "Worker's Comp Bill Encounters Snags in Md.," Washington Post, Feb. 18, 1987, at B1, Exhibit 7.

would exacerbate this already-serious problem.

C. Costs of Medical Surveillance

S. 79, as currently drafted, may impose costs of medical surveillance on employers in situations where it is not warranted. These costs would be particularly significant to small businesses, which may be forced to use funds for medical surveillance that otherwise would be allocated to other employee benefits.

Medical surveillance can be very expensive. SOCMA has conducted a survey of the current medical surveillance practices of its member companies. Approximately 75 percent of the responding companies conduct medical surveillance programs. These programs cost an average of about $175 per employee per year.[9] Moreover, there are significant indirect costs associated with medical surveillance that are difficult to quantify. S. 79 would require companies to incur both the direct costs of perhaps very expensive and sophisticated testing and the costs associated with

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9/ Medical surveillance is performed in a variety of ways: full-time in-house physicians (15 percent of responding companies); physicians in-house on a part-time basis (30 percent); local clinic or hospital (50 percent); mobile medical service (35 percent). (Percentages add up to more than 100 because some companies use more than one method.)

transportation to a designated facility or approved physician, lost work time, and perhaps replacement help.[10]

The aggregate costs of the monitoring required by S. 79 would be substantial. In 1977, the National Institute for Occupational Safety and Health (NIOSH) conducted a study of the costs of notification and medical surveillance. NIOSH concluded:

> Even when consideration is limited to carcinogens substantial costs are involved. The total cost associated with workers currently exposed to OSHA-regulated carcinogens full-time is around $424 million. The cost for both full and part-time workers is nearly $8.5 billion. . . . If consideration is extended to workers currently exposed full-time or part-time to any OSHA-regulated substance, total program costs are estimated to be $54 billion.

NIOSH, "The Right to Know: Practical Problems and Policy Issues Arising from Exposure to Hazardous Chemical and Physical Agents in the Workplace," July 1977 (prepared at the request of the Subcommittee on Labor, Senate Committee on Human Resources), Exhibit 8, at 28. Ten years later, the costs of the program would be even higher.

In view of the substantial expense of medical surveillance, it should be required only in those circumstances

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10/ In many cases, particularly for small businesses involved in specialized operations, replacement personnel may not be available.

where a discernable medical benefit would result. S. 79, as currently drafted, requires the Board to consider populations "likely to benefit" from medical surveillance or health counseling in making the notification decision. However, S. 79 does not provide criteria for determining the extent of medical surveillance, if any, that would be appropriate. SOCMA believes that the Board should be required to consider the costs associated with medical surveillance and the benefits that would accrue in specifying the type and frequency of medical surveillance that would be appropriate.

In this regard, SOCMA has surveyed its members regarding the outcome of existing medical surveillance programs. Medical surveillance has resulted in detection of occupationally-related illnesses only in very rare cases. The typical percentage of monitored employees diagnosed with occupationally-related problems among companies reporting was less than one percent. These results, in conjunction with the high cost of medical surveillance, demonstrate that medical surveillance should not be required except in circumstances where a discernable medical benefit would accrue.

* * * *

S. 79 thus would impose significant impacts in the form of insurance that becomes significantly more expensive or unavailable, increased exposure to liability actions, and costs of medical surveillance. These impacts would be particularly severe for small businesses in terms of direct outlays, ability to allocate resources in view of other regulatory initiatives,[11] and the continued opportunity to compete with larger businesses for capable employees by offering attractive compensation packages. S. 79 may adversely affect the competitive position of small businesses, and it is conceivable that some small businesses may be forced to abandon certain product lines or to close.

SOCMA encourages the Senate to limit the significant impacts that S. 79 would impose on the small business community and its employees. Mechanisms to trigger notification should utilize sound scientific knowledge to ensure that populations notified are truly at risk, and any such notification should have a defined purpose and benefit. OSHA will soon be expanding the hazard communication standard to non-manufacturing sectors. Through the right-to-know provisions of the Superfund Amendments, all individuals, including former employees, are entitled to the same information. These measures, as well as generic standards for medical surveillance and monitoring, which we understand are now under consideration at OSHA, are appropriate vehicles for

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11/ Small businesses are currently faced with a significant "resource crunch" in complying with other regulatory initiatives, such as the hazard communication standard and the Emergency Response and Community Right-to-Know provisions of the 1986 Superfund Amendments.

implementing the purposes of S. 79 without provoking a crisis in the small business community.

If we can be of further assistance, please do not hesitate to contact Judy Mokhtari, Manager, Occupational Safety and Health, at (202) 659-0060.

SYNTHETIC ORGANIC CHEMICAL
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March 5, 1987

EXHIBITS

1. Committee on Risk Classification, American Academy of Archives, "Risk Classification Statement of Principles," June 1980

2. Statement of the Blue Cross and Blue Shield Association on S. 2050, May 15, 1986

3. D.C. Law 6-132

4. Stross, et al., report on "Human Health Effects of Exposure to Polybrominated Biphenyls," 58 Toxicology and Applied Pharmacology 145 (1981)

5. White House Conference on Small Business, A Report to the President of the United States, Nov. 1986

6. "Chemicals Go to Captives for Coverage," Chemical Week, Feb. 11, 1987, at 68

7. "Worker's Comp Bill Encounters Snags in Md.," Washington Post, Feb. 18, 1987

8. NIOSH, "The Right to Know: Practical Problems and Policy Issues Arising from Exposure to Hazardous Chemical and Physical Agents in the Workplace," July 1977

(EDITOR'S NOTE: Due to printing limitations and in the interest of economy, the Exhibits above were retained in the files of the Committee.)

Senator QUAYLE. Our next witness, on behalf of the American Farm Bureau Federation, is Mr. James F. Patterson. Welcome. We are glad to have you.

Mr. PATTERSON. Senator Quayle, my name is Jim Patterson. I am a fruit grower from Ohio and President of the Ohio Farm Bureau Federation. Today I speak for the American Farm Bureau Federation.

The American Farm Bureau Federation is the nation's largest general farm organization, with a current membership of 3.5 million families in 49 States and Puerto Rico, including three-fourths of the commercial farms and ranchers in this country.

The Farm Bureau is a voluntary, nonprofit organization, financed by annual dues paid to more than 2,700 County Farm Bureaus. Some 750,000 farmers and ranchers are employers who would be affected by the enactment of Senate Bill 79.

We appreciate the steps taken by the sponsors of this legislation to respond to some extent to the concerns raised by Farm Bureau and other employer representatives, as well as the Administration, concerning last year's bill.

However, those concessions are not sufficient to eliminate our concerns and end our opposition to this legislation.

The Occupational Safety and Health Administration of the Department of Labor has been given broad authority to regulate in the field of occupational safety and health and has the needed expertise to carry out that responsibility. If a part of that role needs to be performed by the Department of Health and Human Services, it should be in an advisory capacity to the Department of Labor so that employers can deal with one department rather than two.

In addition to our concern about the unnecessary duplication in cost of the proposed new program, we believe the definition of "population at risk" contained in section 3 of the bill is inadequate since it could be based on only one study. Senate Bill 79 defines "occupational health hazard" to mean:

> Any harmful chemical, physical or biological agent, industrial or commercial process or activity found in the workplace for which there is statistically significant evidence, based on at least one study conducted in accordance with established scientific principles, that acute or chronic health effects may occur on exposed employees.

Because it requires only one study, and because of the vague phrase, "may occur," it appears to be an unnecessarily weak standard that would be prone to bureaucratic zeal. This bill virtually guarantees increased litigation and liability, when employers and others in this country are already caught in a rising tide of liability. This prospect is very troublesome to farmers and ranchers.

A finding by an official agency of the Federal government that those who work in a particular occupation are members of a population at risk would carry considerable weight in compensation proceedings and

The implications of this legislation in the area of agricultural employment are very serious. Most agricultural employment consists of temporary and seasonal workers who work at any one work site or for any one employer for short periods of time. Documentation of these workers is at best skimpy. It is literally impossible for an agricultural employer to maintain any kind of credible list of such employees over an extended period of time. Such an employer would have no way to communicate with a great many persons previously employed.

It is not clear to us in reading Senate Bill 79 to what extent employers would be obliged to participate in the employer notification process.

Senator Quayle, as you and other members of this Committee know, this is not the best of times for this nation's farmers and ranchers. The cost of hired labor is the fifth or sixth largest cost of production input in agriculture.

Any proposal that appears likely to add to that cost at this time causes us grave concern. If this bill is enacted, it would lead to widespread and costly medical monitoring and testing, causing an escalation in the cost of health, liability and workers' compensation insurance. Our farmers are struggling desperately right now to restore their ability to compete in the world market.

Most of the farms in this country are small- and medium-sized family operations with ten or fewer employees. We fear that the medical monitoring requirements of this bill would place a heavy burden on such farmers and force even more of them out of business.

The Environmental Protection Agency, which has the statutory authority to regulate the use of pesticides and other agri-chemicals, is well along in the process of expanding the scope of its existing farm-worker protection regulations.

Your bill, Senator Quayle, proposes a more flexible and scientific approach to worker notification of risk. We urge that your proposal be given full consideration and that the procedures proposed in Senate Bill 638 be carried out before the appointment of a Risk Assessment Board and before the other requirements of Senate Bill 79 are initiated.

We appreciate the opportunity to present our views.

Senator QUAYLE. Thank you very much, Mr. Patterson.

[The prepared statement of Mr. Patterson follows:]

STATEMENT OF THE AMERICAN FARM BUREAU FEDERATION TO THE LABOR SUBCOMMITTEE OF THE SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES REGARDING S. 79 -- THE HIGH RISK OCCUPATIONAL DISEASE NOTIFICATION AND PREVENTION ACT OF 1987

Presented by James F. Patterson, President,
Ohio Farm Bureau Federation
March 9, 1987

The American Farm Bureau Federation is the nation's largest general farm organization, with a current membership of 3.5 million families in 49 states and Puerto Rico, including three-fourths of the commercial farms and ranches in this country. Farm Bureau is a voluntary, nonprofit organization, financed entirely by annual dues paid to more than 2,700 County Farm Bureaus.

Some 750,000 farmers and ranchers are employers who would be affected by the enactment of S. 79.

We appreciate the steps taken by the sponsors of this legislation to respond to some extent to the concerns raised by Farm Bureau and other employer representatives, as well as the Administration concerning last year's bill. However, those concessions are not sufficient to eliminate our concerns and end our opposition to this legislation.

The Occupational Safety and Health Administration of the Department of Labor has been given broad authority to regulate in the field of occupational safety and health and has the needed expertise to carry out that responsibility. If a part of that role needs to be performed by the Department of Health and Human Services, it should be in an advisory capacity to, the Department of Labor so that employers can deal with one Department rather than two.

In addition to our concern about the unnecessary duplication and cost of the proposed new program, we believe the definition of "population at risk" contained in Section 3 of the bill is inadequate, since it could be based on only one study.

S. 79 defines "occupational health hazard" to mean "any harmful chemical, physical or biological agent; industrial or commercial process or activity found in the workplace for which there is statistically significant evidence (based on at least one study conducted in accordance with established scientific principles that acute or chronic health effects may occur on exposed employees. . .)."

Because it requires only one study and because of the vague phrase "may occur," it appears to be an unnecessarily weak standard that would be prone to bureaucratic zeal.

This bill virtually guarantees increased litigation and liability, when employers and others in this country are already caught in a rising tide of liability. This pro~~ject~~spect is very troublesome to farmers and ranchers. A finding by an official agency of the federal government that those who work in a particular occupation are members of a "population at risk" would carry considerable weight in compensation proceedings and/or third-party liability litigation, and we are advised that workers compensation coverage will inevitably become a part of employer liability under this bill.

The implications of this legislation in the area of agricultural employment are very serious. Most agricultural employment consists of temporary and seasonal workers who work at any one worksite or for any one employer for short periods of time. Documentation on these workers is at best skimpy. Many of them have several Social Security numbers, all issued under different names. It is literally impossible for an agricultural employer to maintain any kind of credible list of such employees over an extended period of time. Such an employer would have no way to communicate with a great many persons previously employed. It is not clear to us in reading S. 79 to what extent employers would be obliged to participate in the employer notification process.

Mr. Chairman, as you and other members of this Committee know, this is not the best of times for this nation's farmers and ranchers. The cost of hired labor is the fifth or sixth largest cost of production input in agriculture. Any proposal that appears likely to add to that cost at this time causes us grave concern. If this bill is enacted, it would lead to widespread and costly medical monitoring and testing, causing an escalation in the cost of health, liability and workers compensation insurance. Our farmers are struggling desperately right now to restore their ability to compete in the world market.

Most of the farms in the country are small and medium-sized family operations with 10 or fewer employees. We fear that the medical monitoring requirements of this bill would place a heavy burden on such farms and force even more of them out of business.

The Environmental Protection Agency, which has the statutory responsibility to regulate the use of pesticides and other agricultural chemicals, is well along in the process of expanding the scope of its existing farmworker protection regulation. Farmers will soon be faced with a wide range of new requirements in that regulation, including worker notification, which should be adequate to prevent and monitor health problems that may arise from exposure to such materials.

We urge the Committee to reject enactment of S. 79 in its present form. If the Committee determines that additional attention needs to be given to prevention and early detection of occupationally-induced diseases, it should instruct the Occupational Safety and Health Administration, to develop or coordinate such a program with the assistance of NIOSH or other agencies in the Department of Health and Human Services.

This bill would create a new federal entitlement program that would inevitably expand in scope and cost to both employers and taxpayers in general. We have seen it happen time and time again.

The huge federal deficit that now hangs over and threatens the future viability of our economic system and our way of life requires every member of the Congress and every Committee to explore the least costly way of addressing problems that most would agree need to be addressed.

Senator Quayle has a bill. That proposes a more flexible and scientific approach to worker notification of risk. We urge that Senator Quayle's proposal be given full consideration and that the procedures proposed in the Quayle bill be carried out before the appointment of a Risk Assessment Board and before the other requirements of S. 79 are initiated.

We appreciate the opportunity to present our views.

Senator Quayle. The next witness is Wallace Parker, who is the Chairman of the Safety and Health Committee of the Associated General Contractors of America.

Mr. Parker, welcome.

Mr. Parker. Mr. Chairman and members of the Subcommittee, my name is Wally Parker. I am President of Norcoast Beck Constructors, a building and heavy construction firm in Anchorage, Alaska. I am here today representing the Associated General Contractors of America.

My oral presentation will be an abbreviated version of AGC's written statement, which has been provided for the record.

AGC and its member companies share this Committee's longstanding commitment and objective of establishing a safe and healthy working environment for our nation's workers. However, S. 79, the High Risk Occupational Disease Notification and Prevention Act, is completely inappropriate for the construction industry, and the construction industry should be excluded from its coverage.

Because of the failure to exclude the construction industry, AGC and its members oppose passage of the bill.

Many of the provisions of the bill are unnecessary as applied to the construction industry, since they duplicate existing statutes or regulatory standards. The potential yet limited risk of construction and employee exposure to hazardous substances has already been identified and addressed by the Occupational Safety and Health Administration, or OSHA.

Occupational safety and health standards for the construction industry already direct employers in the proper training and handling of hazardous materials.

OSHA is also currently considering an Advisory Committee on Construction Safety and Health recommendation to promulgate additional, yet separate, Hazard Communication Standards for the construction industry. The Hazard Communication Standard would focus on employee health while on the job by providing methods of prevention, employee protection and training.

Any regulation or legislation on hazard notification must consider the low incidence rates of occupational illness for construction.

Based upon the Bureau of Labor Statistics data, occupational illnesses in construction are almost exclusively associated with repeated trauma such as noise-induced hearing loss and other conditions due to repeated motion, pressure, or vibration and account for three of every five recorded illnesses.

The typical construction employee rarely experiences extended or concentrated exposure to hazardous materials. Where frequent exposure may occur during the construction of additions to existing hazardous waste sites, any new standard or legislation should be limited specifically to those situations.

Additionally, S. 79 fails to consider specific aspects of construction industry settings such as the multi-employer worksite. In this setting, the construction jobsite is comprised of many employers, some of which may be working with hazardous materials, and others not. Employees of those employers not working with hazardous substances may have a minimal or unmeasurable exposure, and yet they too fall into the risk category. The bill does not address this particular issue with respect to employer liability.

In light of these facts and statistics, AGC urges that any Hazard Communication Standards or legislation recognize the limited nature of construction employee exposure, recognize the limited types of construction or maintenance operations where exposure to hazardous substances may occur, and recognize that the construction industry is composed of thousands of small, highly competitive businesses that should not be subjected to yet another unnecessary legislation and resultant regulation.

S. 79's provisions have the potential to create unfounded claims, employee uncertainties, and increased liability and insurance costs and ultimately and explosion of litigation which will prove impossible for small, highly competitive contractors.

AGC appreciates the opportunity to commend on S. 79 and urges the Subcommittee to consider the ramifications of the bill in the highly competitive decentralized construction industry, an industry of thousands of small firms with high labor turnover and an industry in which exposure to high-risk occupational disease cannot be equated to or addressed by standards applicable to hazardous substance manufacturing or storing.

We recognize that as an alternate to S. 79, Senator Quayle has proposed legislation to address notification of employees exposed to hazardous substances. Based on the provisions as currently contained in Senator Quayle's proposal, AGC believes that the alternative is a more appropriate approach which begins to consider the complexity of the problem and the fact that there is no one solution, but a series of solutions, based upon a sound, factual basis.

We continue, however, to be concerned about any proposal that does not specifically recognize existing safeguards and unique industry circumstances.

Mr. Chairman, this concludes my testimony, and I would like to thank you for the opportunity afforded me to comment before this Committee.

Senator Quayle. Thank you very much, Mr. Parker.

[The prepared statement of Mr. Parker follows:]

Testimony

of the

Associated General Contractors of America

to the

Senate Labor and Human Resources Committee

March 9, 1987

on

S. 79 - The High Risk Occupational Disease

Notification and Prevention Act of 1987

SKILL RESPONSIBILITY INTEGRITY

AGC is:

- More than 32,500 firms including 8,000 of America's leading general contracting firms responsible for the employment of 3,400,000 plus employees;
- 106 chapters nationwide;
- More than 80 percent of America's contract construction of commercial buildings, highways, industrial, and municipal - utility facilities;
- Over $100 billion of construction volume annually.

The Associated General Contractors of America (AGC) appreciates the opportunity to express its views regarding S. 79, the "High Risk Occupational Disease Notification and Prevention Act of 1987." AGC shares the Committee's objective of establishing a safe and healthy working environment for our nation's workers; S. 79 however, is completely inappropriate for the construction industry and consequently the construction industry should be excluded from its coverage. Absent such exclusion, AGC opposes passage of S. 79.

S. 79 - The High Risk Occupational Disease Notification and Prevention Act of 1987 would mandate research and surveillance of employee exposure to health hazards, establish procedures to identify worker populations at risk and provide for employee notification and counseling, health facilities, and enforcement authorities, including provisions for employee discrimination complaints.

Existing Construction Industry Standards

Many of the provisions of the bill are unnecessary as applied to the construction industry since they duplicate existing statutes or regulatory standards.

The potential, yet limited risk of construction employee exposure to hazardous substances, has already been identified and addressed by the Occupational Safety and Health Administration (OSHA). The Occupational Safety and Health Standards for the construction industry (29 CFR Part 1926) directs the employer in the proper training and handling of hazardous materials. Specifically, 1926.21(b)(2) (Safety Training and Education) states, "The employer shall instruct each employee in the recognition and avoidance of unsafe conditions and the regulation applicable to his work environment to control or eliminate any hazards or other work exposure to illnesses." In addition, the Occupational Safety and Health Act already requires employers to notify employees regarding hazardous substance exposure and to retain all pertinent medical records for a period of 30 years.

The Occupational Safety and Health Administration (OSHA) is also currently considering an Advisory Committee on Construction Safety and Health recommendation to promulgate additional, yet separate, Hazard Communication Standards for the construction industry. The Hazard Communication Standard would focus on employee health while on the job by providing methods of prevention, employee protection and training.

Morever, there are 33 states which have promulgated rules concerning employee exposure to hazardous substances. Also the Environmental Protection Agency, under the Resource Conservation and Recovery Act has promulgated standards concerning hazardous substances.

Limited Nature of Construction Employee Exposure

Any regulation or legislation on hazard notification must consider the low incidence rates of occupational illnesses for construction. Based upon the Bureau of Labor Statistics data, occupational illnesses in construction are almost exclusively associated with repeated trauma (noise-induced hearing loss and other conditions due to repeated motion, pressure, or vibration) and account for 3 of every 5 recorded illnesses.

The typical construction employee rarely experiences extended or concentrated exposure to hazardous materials. Where frequent exposure may occur during the maintenance of hazardous waste sites, any new standard or legislation should be limited specifically to those situations.

In light of these statistics, AGC urges that any hazard communication standards or legislation 1) recognize the limited nature of construction employee exposure, 2) recognize the limited types of construction or maintenance operations where exposure to hazardous substances may occur, and 3) recognize that the construction industry is composed of thousands of small highly competitive businesses that should not be subjected to yet more unnecessary legislation and resultant regulation.

Specific Provisions of S. 79

Under S. 79 employees would be notified by the government or employers based on the determination of a Risk Assesment Board that they are in a class or category of employees exposed to a particular substance which may cause disease. The Bill provides for a goal of notifying 300,000 persons a year, with a minimum quota of 100,000 and also for the notification of employees who may have been exposed to a hazard anytime during the last 30 years. AGC believes that this quota approach to notification and classification is inappropriate because employees, such as those under the quota, in construction, having even minimal or incidental exposure would be considered at risk of disease.

S. 79 also fails to consider specific aspects of construction industry settings such as the multi-employer worksite. The construction jobsite is comprised of many employers, some of which may be working with hazardous substances. Employees of those employers not working with a hazardous substances may have a miniscule exposure and still fall into the risk category.

e Bill does not address this particular issue with respect employer liability.

S. 79's provisions have the potential to create unfounded claims, employee uncertainties, and increased liability and insurance costs and ultimately an explosion of litigation which will prove burdensome for small highly competitive contractors.

Section 9 of S. 79 - Employee Discrimination - provides that no employer, insurance carrier, or other person shall discharge or in any manner discriminate against any employee on the basis that the employee is or has been a member of a population that has been determined by the Secretary to be at risk of disease. This section would create serious problems for employers of persons who, during employment under a prior employer, were subjected to an exposure which subsequently resulted in a risk classification. The current employer would clearly be in a Catch 22 situation. Should the employer decide against hiring a prospective employee because he or she has been classified in a risk category the employer would be guilty of discrimination. Yet if the employer hires the risk classified individual he becomes liable. In construction, with its high employee turnover rate, this situation will be repeated over and over again.

Section 10 of the Bill provides for injunctive relief, and subrogation. This section would require that any health care insurance system cover the cost of medical monitoring and treatment triggered by the notification. In the case of the construction industry with its high rates of employee turnover and limited, if any, exposure such activities would constitute an insurance subrogation claim against a workers compensation program or insurance carrier. Ultimately, the cost of workers compensation programs will rise unnecessarily, causing construction costs to increase as a result.

AGC appreciates the opportunity to comment on S. 79 and urges the Subcommittee to consider the ramifications of the bill on the highly competitive decentralized construction industry. This industry of thousands of small firms with high labor turnover is an industry whose exposure to high risk occupational disease cannot be equated to, or addressed by, standards applicable to hazardous substance manufacturing or storing.

AGC believes in the maintenance of a safe and healthful work environment for all employees. AGC does not believe that S. 79, "The High Risk Occupational Disease Notification and Prevention Act of 1987," represents a step in that direction in the construction industry. AGC opposes enactment of S. 79 since it fails to exclude the construction industry from coverage.

Senator QUAYLE. Our final witness of this panel is Dr. Peter Ruane, Chairman and Treasurer, Small Business Legislative Council.

Dr. Ruane, welcome.

Dr. RUANE. Good morning, Senator Quayle.

I am Pete Ruane, representing today the Small Business Legislative Council, which is a permanent coalition of 90 trade associations who collectively represent over 4 million small businesses, including the entire spectrum of U.S. industry.

The major point today of our testimony is the impact of the specific cost of implementing the proposed bill. We anticipate that implementation of this act would translate to a severe adverse impact on both jobs and companies throughout our nation.

The SBLC's concern is also in the area of the growing public policy arena of mandated benefits. We view this particular legislation as part of that emerging concern and would be also opposed to mandating additional benefits.

Recently the SBLC held its annual issues' conference, and among the 50 or so issues that the attendees evaluated, the High Risk Act came out number 12 among our top 20. We also have a major concern with the aforementioned workers' comp increases. The tort liability insurance crisis that would be exacerbated by this legislation.

We feel that the existing OSHA program should be given sufficient time to work. I refer specifically to the OSHA Hazard Communication Standard that was just put into place in May of 1986. In our statement, we point out a very preliminary estimate of the potential cost per employee in a typical small business. That cost is conservatively estimated to be roughly $3,500, and that does not include the major increase in workers' comp and health insurance rate increases that small business would anticipate.

We also point out that the workers may not in fact take the tests that are recommended. Those who perhaps have individual personal problems or may be involved in drug or alcohol use may not even participate in the testing.

We have looked closely, Senator Quayle, at your own proposal and feel this is a more reasonable alternative to S. 79. We view this as an important first step in considering this problem.

Now, lest we be misunderstood, we want to underscore the fact that we are not against workers' rights to be notified about exposure to hazards and would in fact support those existing programs that do this very thing.

We, however, feel that mandating an additional notification process is not a good idea at this point. We feel that the impact on small business has not been analyzed adequately; the specific economic cost has not been portrayed in any of the ratings to which we have been exposed, and we would urge this Committee to look into that matter as it considers this legislation.

And finally, we would point out that we would support your bill, Senator Quayle, as a much better alternative to dealing with this serious problem.

Thank you.

Senator QUAYLE. Thank you very much, Dr. Ruane.

[The prepared statement of Dr. Ruane follows:]

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TESTIMONY

of

T. Peter Ruane
Treasurer

Small Business Legislative Council

Before

The Subcommittee on Labor of the

Committee on Labor

United States Senate

March 9, 1987

1025 Vermont Avenue NW/Suite 1201/Washington, D.C. 20005/(202) 639-8500

My name is T. Peter Ruane and I am the Treasurer of the Small Business Legislative Council (SBLC), Chairman of SBLC's Employment Issues and Pension Law Committee and President of the National Moving and Storage Association. The SBLC is a permanent, independent coalition of ninety trade and professional associations who share a common concern for the future of small business. Our member associations represent the interests of over four million small businesses.

We support a healthful workplace and have no disagreement with the objective of testing, early identification, and treatment of disease. There are, however, constructive points which have been made by organizations who oppose S.79 in its present form which would appear to merit the Committee's careful consideration.

We have one all consuming concern that to our mind eclipses all others and which will be the focus of our testimony today. That concern is the potential cost of implementing the proposal and its impact on jobs and companies.

As you know, millions of U.S. manufacturing jobs have been lost in recent years because of foreign competition. Our trade deficit last year approached $200 billion. There are many reasons for this imbalance, but one of the biggest is the price of U.S. products. It is only reasonable to assume that if there are significant additional costs imposed by the proposal on U.S. manufacturers, those costs will be reflected in product price. Our trading partners, who have no such responsibilities under the proposal and no such costs, will face no such price increases. The decline in competitiveness of U.S. products would result in lower sales by U.S. firms and job losses.

We agree that there are significant economic and social costs resulting from not testing for and treating, if necessary, occupational illness. We hope you will agree that there are also significant economic and social costs associated with compliance and potential increase in unemployment.

We are in the midst of a shift in public policy in this country. The first signs of this change emerged in the Consolidated Reconciliation Act of 1985 (COBRA). In COBRA we imposed a requirement on employers to provide the opportunity for employees to continue their coverage when they retire or are laid off. In the second session of the 99th Congress, legislation to provide "parental leave" gained notoriety. In the 100th Congress, there are already proposals on parental leave, an increase in the minimum wage and mandated health insurance for all employees, all in addition to the bill now before us. The public policy shift is a transfer of the responsibility for social and environmental goals to the business sector, particularly small businesses. It seems like a simple solution; make it a mandate and let business worry about it. At what point, however, do we reach the breaking point? Each one of these programs might look attractive on its merits and the price tag for each might not seem so bad. In the aggregate, will these mandates result in failure of many small businesses? There is only so much a small business can absorb or pass on the customer.

We recently held our 1987 Issues Conference. At that conference, we reviewed more than three dozen possible issues and at the end of the day we voted on twenty priorities. The twelfth priority for SBLC in the 100th Congress was the following recommendation:

HIGH RISK OCCUPATIONAL DISEASE NOTIFICATION AND PREVENTION ACT. The High Risk Occupational Disease Notification and Prevention Act establishes a new federal program to individually notify past and present employees who are more likely than similar populations to develop an occupational disease. The employee is then encouraged to undergo medical monitoring. The present employer must pay for the tests unless that employer was not the one responsible for an exposure to the particular hazard associated with the disease. The bill also establishes an eight member Federal Risk Assessment Board in the Department of Health and Human Services to assess health studies and determine which employees are in increased risk groups. Eventually, each state would have an occupational and environmental health center with research authority and access to all federal employment-related files.

The bill authorizes a government expenditure of $25 million for each of two years, but estimates are that the costs will actually be much higher. The government has not even assessed the costs to the nation's businesses or the unemployment which would result. In addition, the legislation would increase the cost of worker's compensation and health insurance and escalate the liability suit crisis, according to insurance industry estimates. The bill places administration of the program within the Department of Health and Human Services and places the enforcement authority in the Department of Labor.

Moreover, there is no indication that the Occupation Disease Notification Act will give any protection. It merely requires the employee to be notified that if he has an occupational disease, it could have been caused by his occupation and it suggests medical monitoring.

The proponents of the bill declare that its primary purpose is to detect and prevent cancer, but only five percent of cancers in our society are occupationally related as was pointed out in the minority report in the 99th Congress.

The need for additional health centers and expenditures of these federal dollars during this austere time has not been demonstrated. The few hearings held brought forth no testimony to indicate that current hospitals or medical clinics are incapable of medically monitoring or evaluating notified workers. Existing hospitals are capable of dealing with the medical needs of notified workers.

The Department of Labor, in May of 1986 broadened and strengthened the OSHA Hazard Communication Standard to require employers who manufacture, distribute and import hazardous substances to notify employees of health hazards in the workplace and train those employees in how to handle those hazards safely. OSHA is in the process of expanding the scope of coverage of the rule to all workers exposed to hazardous chemicals. In addition, more than 35 states and localities have similar laws. This approach should be given a fair opportunity to work before we add a complex, costly, and untested program of post-exposure risk assessment and notification.

As unpleasant as it will be, this Committee will likely have to make some very hard choices. The possible trade off between testing and treating workers with occupational illnesses and eliminating jobs poses a great moral dilemma. We are suggesting that the choices you face must be made with the most accurate hard data or best estimates you can obtain. As we reviewed the record of last year's hearings, and the information available today, it became apparent to us that we still lack complete quantitative data to facilitate any decision with respect to the alternatives.

Another small business organization has helped by suggesting at the February 24, 1987 hearing, a method to analyze the cost and benefits. We have taken the liberty of updating the data available based on new information we have determined. Certainly, much of it could be off in either direction. We believe that Congress should obtain the additional data and refine these numbers until they have confidence in them before making decisions.

As the attached chart demonstrates, there is a potential for at least $3,513.03 in additional annual costs per worker associated with firms providing occupational disease notification. This does not include significant increases in worker compensation insurance costs or health insurance costs. This is well beyond any reasonable standard of "undue hardship" for American business.

We are not suggesting that S.79 would not significantly benefit workers. We are suggesting that if refined cost estimates show a significant impact on competitiveness, some other means of funding that effort should be found in order to save jobs.

In the meantime, much has already been accomplished. OSHA's hazard communication program has been implemented in some industries. We believe workers will seek testing and treatment if necessary as a result of the OSHA hazard communication program.

Will all workers agree to take the employer provided tests called for under S.79? We do not believe they will. Some, particularly those who may need them the most, those with drug or alcohol problems, will claim it is a violation of personal rights.

Two things can be done while the data needed for a cost benefit analysis of S.79 is refined. First, a study can be made of the early impact of the implementation of OSHA hazard communication regulations. How many affected workers have sought testing and treatment, if necessary, as a result of the notification. We believe that this information would be helpful both in refining pending proposals as well as evaluating the need for additional legislation.

Another alternative is the proposal introduced by Senator Quayle. Granted, it is more modest in scope but our first reading is that its impact on U.S. competitiveness and jobs would be minimal. Its positive impact on worker health is as great as would be S. 79. However, its costs in terms of American jobs is not so great.

Were it not for the precarious position of American business, and especially small business, with respect to foreign competition, perhaps we could afford to be more bold.

Until such time as U.S. competitiveness is restored and industrial base revitalized, we should move methodically but cautiously to assure that improvements in health standards do not cause more suffering as a result of unemployment than they alleviate through early medical treatment.

We believe that the small business community has offered an appropriate format for the analysis of the costs and we call on the committee, its staff, the insurance industry, and other business interests, and labor unions to help generate additional data needed to fill in the blanks and refine existing data.

FORMULA FOR DETERMINING JOB LOSSES-

EMPLOYER FUNDED OCCUPATION DISEASE NOTIFICATION AND TESTING

	Workers Affects	21 Million [1]
1)	Notification Costs (each, optional)	$ 20 - 27.50 [2]
2)	Surveillance/Testing Costs (each)	$ 20 - 1,000 [3]
3)	Transportation, Food, Some Lodging (each)	$ 20 [4]
4)	Cost of Idle Equipment (each)	$ 133.20 [5]
5)	Workers Compensation Rate Increase (current $250 each)	? [6] [7]
6)	Health Insurance Rate Increase (current $2,205 each)	? [8]
7)	Additional Legal Fees, Settlements and Judgments	$2,333.33 [9]
8)	Total Costs	$2,526.53 (low) - $3,513.03 plus Line 5 + Line 6
9)	Product Price Increase (Line 8 - Sales Per Employee)	?
10)	U.S. Jobs Lost Due to U.S. Product Price Increase	?

ENDNOTES

1) "One in every five American workers (approximately 21 million) currently may be exposed on either a full or part-time basis to OSHA-regulated hazardous substances". "The Right to Know", NIOSH, July 1977.

2) NIOSH estimate (p.45, 1986 hearings), 2/18/87 Wall Street Journal, p.1.

3) Tests would include, among other substances benzene, asbestos, arsenic, chromium, chromatic pigments, mesa silica or cotton or coal dust. Estimated costs range from $20-200 per test or series of tests. Also "the cost impact of such monitoring could be significant" (statement of John Abbott and Patrick Cormody, May 15, 1986 hearing, p.208). Also 2/18/87 Wall Street Journal article. Also July 19877 NIOSH study, "The Right to Know", p.26, 27, Chart 4.

4) "will be made available by such employer at no cost to the employee..." p.20 lines 3-4 S.79. There is reason to believe that qualified medical personnel with either not be available or not be geographically convenient to a small manufacturer in a rural area. Reasons for that belief are "there is a lack of adequately trained medical and human service professionals, as well as appropriately staffed and equipped health facilities to recognize, diagnose and prevent occupational illnesses (S.79, findings p.3, lines 12-15) also number of individuals each year to be added to testing program (100,000-300,000) (p.10, lines 15-23). Also the requirement that health centers provide education, training and technical assistance to personal physicians and other professionals serving those employees and offer those services for employees as well (S.79, p.20, lines 13-19) also the requirement that "no school of medicine may receive federal financial assistance...unless it offers a course of study on occupational disease (p.22, lines 6-12).

   Assumes 1/3 of workers will travel under 10 miles, 1/3 will travel approximately 30 miles, and 1/3 will travel 100 miles (or 47 miles average at $.25 mile) and meals for 20% (@5.00 each) plus lodging for 10% (@$35.00 each) $11.75 + $1.00 + $3.50 = $16.25.

5) Assume 1/3 of workers will be out two hours, 1/3 four hours, and 1/3 eight hours. Based on operator of $250,000 machining center, 90% financed at 12% for 5 years or $33.30 per hour.

6) Unknown "state workers' compensation systems would be inundated with claims because of the fear of becoming disabled". Statement of Charles Coakley, Senior Counsel, American Insurance Association, May 15, 1986 hearings p.199. Also Wall Street Journal 2/18/87 p.1.
7) Unknown "the cost of health insurance would increase dramatically if S.2050 were enacted". Same.

8) Unknown "the net result would be an overall increase in claim expenses to the employer". Statement by John Abbott and Patrick Cormody, Health Insurance Association of America p.218.

9) There are at least some indications this could be high. An Augusta, Georgia company with 800 workers reportedly instigated an employee occupational disease notification program. Aggregate total of damages sought in subsequent employee suits was reportedly $358 million. This works out to $477,500 per worker.

   A February 18, 1987 Wall Street Journal article "Lawyers Lead Hunt for New Groups of Asbestos Victims", attorneys are engaging in aggressive client recruitment efforts involving direct mail, and free mobile tests to workers who use the firm to bring suit. The article states that the efforts are swamping court dockets and quotes Calvert Crary of Bear Sterns & Co. who believes the asbestos lawyers are naturally looking to widen their sphere.

   While these may be extreme examples, more data is definitely needed on ratios between law suits and settlement costs in occupational disease notification circumstances.

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National Association of Minority Contractors
National Association of Personnel Consultants
National Association of Plumbing-Heating-Cooling Contractors
National Association of Realtors
National Association of Retail Druggists
National Association of Small Business Investment Companies
National Association of the Remodeling Industry
National Association of Truck Stop Operators
National Association of Women Business Owners
National Candy Wholesalers Association
National Chimney Sweep Guild
National Coffee Service Association
National Council for Industrial Innovation
National Electrical Contractors Association
National Fastener Distributors Association
National Grocers Association
National Independent Dairy-Foods Association
National Moving and Storage Association
National Office Products Association
National Parking Association
National Precast Concrete Association
National Shoe Retailers Association
National Society of Public Accountants
National Tire Dealers & Retreaders Association
National Tooling and Machining Association
National Tour Association
National Venture Capital Association
Opticians Association of America
Petroleum Marketers Association
Printing Industries of America, Inc.
Retail Floorcovering Institute
Small Business Council of America, Inc.
Smaller Manufacturers Council
Society of American Florists
Specialty Advertising Association International
United Bus Owners of America
Urethane Foam Contractors Association
Web Sling Association

Senator QUAYLE. Let me ask Mr. Patterson a question first. There is a lot of attention given today to the small family farmer. You referred to the plight of the farmers and some of the problems in your testimony. I wonder if you might just describe what you think the impact of S. 79, if it was passed as it is right now, would be on the small family farmer.

You have a farming background. I am thinking of the average small family farmer; what kind of an impact do you think this would have on that operation?

Mr. PATTERSON. I think the small family farmer first of all tends to keep many less records that he probably should, admittedly. But when you look back through a period of time, if there was some chemical, for example, that he may or may not have been using, and say he had high school-age boys, for example, helping him make hay—to what extent do you have to keep records and to what extent may they have been exposed?

Then, when you get into the overall question of the use by farmers and the use of migrant labor and that type of thing, where people are moving and this month are picking something in Missouri and next month are picking something in Ohio and next month are picking something in Michigan, how do you keep track of this tremendous movement?

When you get into the area of notification, what liability is this going to force onto the farmer; to what extent is he going to have to keep records and how far back?

And then, you know, about the farmer himself—what if we found from one study that phosphorous or nitrogen or potash were a carcinogen, for example. What does that do to the total farming community, for every farmer who has used that in a fertilizer program for years and years and years, just as an example. It could be triggered by one study, for example.

Senator QUAYLE. So what psychological impact or effectiveness impact could this legislation possibly have on the farming community?

Mr. PATTERSON. Well, to the extent that the legislation would be enacted, it could go all the way to simply increasing the burden upon the records and paperwork they need to keep to probably some—particularly if they got into a situation where they had used a chemical, and there was some liability implied or expressed or found—it certainly could force them right out of business.

Senator QUAYLE. So this would be a significant additional burden that would be placed on the family farmer today?

Mr. PATTERSON. We believe that is right, yes.

Senator QUAYLE. Let me take Mr. Patterson's concern and ask a question of the panel. You talked about the notification process and a lot of the workers coming in and being able to identify where they go, particularly migrant workers who work in Missouri one day and Ohio the next, or Indiana. Then, also, you got into the liability impact on the farmer.

What part of the legislation in this whole area concerns you all the most? There are basically two parts. One is the actual notification process and how we go about notifying employees of certain risks of getting certain diseases. The other part deals with the liability, the medical monitoring, the liability that would go to the employer, the possibility of lawsuits.

Which area is of the most concern to you? I just want to see which one you are more interested in.

Mr. Humphrey?

Mr. **Humphrey**. Senator, let me address the latter of those two points. We are a small chemical company, as I alluded to in the testimony. We cannot self-insure; because of size. . . . Currently we have a noncontributory insurance program; we pay for it. A quick check on the numbers goes something like this: Annually, workmen's compensation, $35,000; product liability, $110,000; Blue Cross/Blue Shield, $120,000; and Major Medical, $45,000. It adds up to about $310,000 on about $9 million. Divide that by about 50 employees, and we are looking at over $6,000 per employee.

What worries SOCMA and myself, I think, is the effect of S. 79 on the folks that write insurance. Since we do not self-insure and turn to the insurance industry for coverage, a catastrophic increase, or being red-lined right out of the ability to turn to coverage on the outside, would be disastrous as far as competitiveness is concerned.

Senator **Quayle**. So your concern is more in the area of liability?

Mr. **Humphrey**. I would say.

Senator **Quayle**. Dr. Ruane, would you agree that of the two, that the liability issue is the one that is of greatest concern?

Dr. **Ruane**. Yes, Senator, absolutely. The onslaught of lawsuits, the rise in insurance rates, workers 'comp, health insurance across-the-board would be our major concern.

Senator **Quayle**. Mr. Patterson, you are nodding your head. That is probably the biggest concern, you think, to the farmers, that potential liability that would go to him?

Mr. **Patterson**. I would think so. I think the liability would be the bigger part of the question. But I think it is almost as big a part of the question on the one study. If you recall, about 18 months ago, there was a material called "alar" that came out in regard to its use on apples. One study, of which there were numerous studies on the other side—but one study has just simply eliminated that product, and it has caused national controversy.

Senator **Quayle**. Mr. Parker, would you agree that the liability issue is a bigger concern or the notification?

Mr. **Parker**. The liability and the costs of workmen's comp. But I would like to address notification for a moment, if I may. We, probably similar to the farmers, employ a very mobile group of employees. I personally was involved with a notification requirement for a Taft-Hartley trust I sit on, and we were required to contact some 3,000 former workers on the Alaska pipeline. I can assure you it was absolutely impossible. It was required by the Labor Department for us to do this, and it could not be done.

Senator **Quayle**. Let me ask just one final question of this panel. Let me give you a choice, and the choice will be A, B, or C. It will be a simple multiple choice response.

I would like to know, as of today, what your preference would be as far as what the Congress ought to do. A would be to have the Metzenbaum approach; B would be to have the Quayle approach; C would be to keep with the current system and the feeling that it is adequate and that we do not need legislation in the area of risk notification.

What would you pick, Mr. Humphrey, A, B, or C?

Mr. **Humphrey**. At the risk of a quick answer, B, with the reservation that SOCMA would get a chance to look at how your bill would finally come out—but B, I think.

Senator **Quayle**. B, with reservations. That was not part of the quiz, but that is all right.

Mr. Patterson?

Mr. **Patterson**. Recognizing that a problem exists, I think we would select B.

Senator **Quayle**. Dr. Ruane?

Dr. **Ruane**. Likewise, we would select B.

Senator **Quayle**. Mr. Parker?

Mr. **Parker**. I would have to select C, as there are plenty of regulations in place and more coming.

Senator **Quayle**. Gentlemen, thank you. I will not tell you who passed, but I think you have a good idea. [Laughter.]

The next panel will include: John Knebel, Earl Arp, and George Rodenhausen.

First, the President of the American Mining Congress, John Knebel, who is accompanied by Bernard Roy.

Mr. Knebel, welcome, and go ahead and proceed.

STATEMENTS OF JOHN A. KNEBEL, PRESIDENT, AMERICAN MINING CONGRESS, ACCOMPANIED BY BERNARD ROY; DR. EARL ARP, DIRECTOR OF HEALTH AND SAFETY, ASHLAND OIL CO., ACCOMPANIED BY DR. GERRY RAABE, MANAGER OF EPIDEMIOLOGY AND MEDICAL INFORMATION SERVICES, MOBIL OIL CORP., ON BEHALF OF THE AMERICAN PETROLEUM INSTITUTE; AND GEORGE RODENHAUSEN, DIRECTOR, ENVIRONMENTAL HEALTH AND SAFETY AFFAIRS, CELANESE CORP., ACCOMPANIED BY DR. BRUCE W. KARRH, VICE PRESIDENT FOR SAFETY, HEALTH AND ENVIRONMENTAL AFFAIRS, E.I. DUPONT DE NEUMOURS AND CO., ON BEHALF OF THE CHEMICAL MANUFACTURERS ASSOCIATION

Mr. **Knebel**. Thank you, Senator. Mindful of your tight situation, we indeed do have a summary statement, and we would ask that you include our entire statement in the record.

Senator **Quayle**. It will be. I will tell all the panel members that your entire statements will be incorporated in the record.

Mr. **Knebel**. The American Mining Congress appreciates the opportunity to present the views of the industry on S. 79. The importance to our nation of a viable and competitive mining industry cannot be overemphasized. Our member companies produce the raw materials upon which our entire economy is based.

We are distressed by the fact that the Congress is once again considering a bill as scientifically flawed and financially disastrous as S. 79. The primary item on the national agenda is the competitiveness and survival of American industry. Extrapolation from the State the government notification pilot program demonstrates that S. 79 could result in liability claims in excess of $112 billion against American industry in the first year of the program.

On these grounds alone, S. 79 warrants a resounding defeat.

While our government grows larger and the Federal budget deficit reaches record levels each year, American industry finds its struggle to be competitive all the more difficult. We believe that S. 79 ignores this national crisis. We hardly believe that a fourth Federal agency to deal with occupational safety and health is either necessary or appropriate at this juncture.

Moreover, if you were to administer the bill in accordance with the intent of its supporters, the program could cost as much as $3 billion per year once it is fully implemented. Now, I grant you, Senator, S. 79 already has 23 cosponsors, and appears to be on a fast track. It has all of the attractive features—a compelling title, small first-year appropriations, and goals as American as apple pie and motherhood. But it simply fails the dual test of whether it is needed and whether it is appropriate for America today.

Please be assured that we in the mining industry, like all other American industries, are committed to protecting the safety and health of our employees. We believe that S. 79 fails to achieve the goal of promoting occupational health.

There are three or four major flaws in the bill that I would like to address here, and of course our detailed statement covers them in-depth.

First of all, we heard earlier today from a panel of distinguished medical doctors and scientists. Dr. Burger has previously noted that the drafters of the legislation have completely ignored the NIOSH Board study which was put out prior to the drafting. We are pleased that you have agreed to include that report in the hearing record.

Secondly, the bill has several procedural problems, and there are safeguards that are missing that we feel are very important. In the procedure for determining what is to be a noticed population, there are unrealistic time frames; a very difficult way to make input; the right of cross-examination is abridged; there is very scant opportunity for judicial review; and by and large, we feel that the decision to make a notification does not or would not have to be supported by substantial evidence.

Third, the financial chaos which would result if this measure were to become law, is well-documented. The unwarranted litigation that would be encouraged by the government making a notification is horrendous. Certainly, we know of the litigious nature of this society today, and if you were to take the study of a few years ago, project it out to the cost, we again see a potential of upwards of $112 billion litigation during the first year of the program.

We think for the Congress at this juncture to adopt such legislation would be both irresponsible and contrary to the best interests of our nation. We in the mining industry have seen devastating effects on our inability to compete with foreign producers. Our written statement includes a table demonstrating our loss of over 500,000 mining-related jobs since 1979.

Certainly, not all of these job losses were caused by governmental action. Many are due to low-cost foreign producers who fail to provide even a modicum of environmental or employee protection.

Yet, rather than assist us in assuring the viability of our nation's bedrock industry by cooperative, flexible, cost-effective programs, far too often we have been faced with huge, unnecessary costs imposed by ill-conceived government action. We believe that S. 79 fits right into that framework. It could well become the worst example of a good intention gone awry.

Senator Quayle, we greatly appreciate your efforts in identifying and shoring up these weaknesses. We pledge our support of your continued efforts to defeat this measure.

Thank you.

Senator QUAYLE. Thank you very much, Mr. Knebel.

[The prepared statement of Mr. Knebel follows:]

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Testimony On

Senate Bill No. 79

"The High Risk Occupational Disease
Notification and Prevention Act of 1987"

Before the

United States Senate

Subcommittee on Labor

of the

Committee on Labor and Human Resources

March 9, 1987

Witnesses:

John A. Knebel, President, American Mining Congress

Bernard Roy, Director of Loss Prevention, AMAX Inc.

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American Mining Congress
Testimony On

S. 79
"The High-Risk Occupational Disease Notification and Prevention Act of 1987"

Before the
Committee on Labor and Human Resources
Subcommittee on Labor
March 9, 1987

The member companies of the American Mining Congress appreciate this opportunity to provide you with our views regarding S. 79, the "High-Risk Occupational Disease Notification and Prevention Act of 1987."

AMC is a national trade association representing the producers of the vast majority of the nation's metals, coal, industrial and agricultural minerals, and the manufacturers of mining and mineral processing machinery, equipment and supplies.

AMC's testimony is the result of a careful analysis by the health and safety experts of our membership. Their comments and views are formulated into an industry-wide position by AMC's Board of Directors' standing Committee on Occupational Health.

As spokesman for the industry, AMC can relay to you our commitment to protecting the safety and health of the miners who produce our nation's minerals. While we certainly share the goal of fostering the health and safety of our employees, we strenuously oppose S. 79.

Our testimony demonstrates that S.79 is unlikely to contribute in a significant manner to the prevention of disease, while holding the potential for disastrous financial consequences. Our industry is the bedrock upon which America's industrial base is founded. Yet, our economic stability is threatened by a number of factors, both within and outside of our nation's borders. Mining employment and production figures including those for the home states the members of this Committee, demonstrate our problem. These numbers are illustrative of the competitiveness issue with which this Congress and Administration are concerned. Yet, S.79 threatens to impact our basic industries even further by adding disastrous and unnecessary costs.

THE DECLINE OF MINING PRODUCTION AND EMPLOYMENT

	PRIMARY PRODUCTION (000 MT)		APPARENT CONSUMPTION[1] (000 MT)		EMPLOYMENT	
	1979	1985	1979	1985	1979	1985
ALUMINUM	4,556	3,500	5,341	4,883	23,000	19,000
COPPER	1,515	1,125	2,339	2,166	41,000	15,900
LEAD	578	489	1,256	1,148	5,500	3,000
MOLYBDENUM	65.3	48.5	33.4	14.1	4,800	2,300
ZINC	472	225	929	960	9,000	4,500
STEEL	123,651	80,740	121,564	97,705	735,000[2]	262,800[2]
TOTAL	**130,837**	**86,128**	**131,462**	**106,876**	**818,300**	**307,500**

1/ Apparent consumption equals U.S. production, plus imports, minums exports and adjustments for inventory changes.

2/ Includes employment in iron ore mining and accounts for a significant market share of coal and other mineral production.

Source: U.S. Bureau of Mine Mineral Production Summaries

Coal Employment

1980	1981	1982	1983	1984	1985	1986
246,000	252,000	249,000	295,000	184,000	187,000	171,000

Source: Bureau of Labor Statistics

More Bureaucracy Is Unnecessary And Counterproductive

Initially, we seriously question the need for S. 79. The statutes creating the Occupational Safety and Health Administration (OSHA) and the Mine Safety and Health Administration (MSHA) require the Secretary of Health and Human Services, through his research arm, the National Institute for Occupational Safety and Health (NIOSH), to conduct research and evaluations. The regulations of these three agencies require a vast array of health protections, training and communication of hazards to the employees. Further, these three agencies have ample existing statutory authority to fill any perceived or real gaps in health protection coverage.

Approximately 500 million dollars of the federal budget is allocated to these three existing safety and health agencies that are charged with promulgating federal standards, enforcement, research, technical assistance and training.

Workers are regularly trained regarding the hazards of workplace exposure to potentially toxic substances. For example, MSHA requires a minimum of 40 hours initial training for underground employees and 24 hours initial training for surface employees. Initial training covers the hazards that an employee may be exposed to and is supplemented on an annual basis by a minimum of at least 8 hours of refresher training. This statutorily mandated training program is oriented to site-specific hazards and includes toxic substance, and protection training.

Under the OSHA hazard communication regulations, employees must be provided with information regarding hazards and the safe handling of potentially toxic materials. Inherent in this training is site-specific education of employees on the potential health effects of their exposures.

Independent of any government requirements, AMC's member companies have ongoing programs to identify potential hazards, and control or eliminate potential employee exposures to these hazards. The large variety of mining and processing operations represented by AMC, and their inherent differences, prohibit an in-depth description of the protective measures that our member companies undertake. However, we can assure you that all of our member companies are committed to the statement in our Declaration of Policy that ". . . pledges [AMC's] continued cooperation in achieving the common goal of all parties involved in safety and health: the protection of the workforce".

In addition to regulatory and company initiatives aimed at identifying and protecting against potential toxic hazards, extensive preventive measures result from government enforcement activities. For example, both MSHA and OSHA conduct extensive industrial hygiene inspections at workplaces. These inspections entail an evaluation of hazards and enforcement action if employees are not being protected. MSHA is mandated to inspect each underground mine at least four times per year and each surface mine twice per year. In many large mining operations one or more MSHA inspectors are at the site every day.

Furthermore, the mining industry is currently undergoing an extensive evaluation of potential health risks through NIOSH's National Occupational Health Survey of Mining. A similar extensive study has already been completed for general industry. This NIOSH mining project alone will provide an in-depth analysis of potential hazards throughout our industry. It involves extensive health data collection through a random site visit program to approximately 900 mines, representing all mining commodities over a 5-year period. AMC is cooperating with NIOSH on this project and has retained an experienced certified industrial hygienist to monitor the project and provide seminars for affected mine operators to assist in making the NIOSH visits a positive experience for mine health programs.

This comprehensive program is being conducted concurrently with NIOSH site-specific health hazard evaluations and substance-specific research projects. Every year NIOSH conducts numerous health hazard evaluations on industrial sites on its own initiative or at the request of industry, labor or other government agencies. Additionally, the Institute conducts research on many potentially toxic substances and processes. For example, in mining alone, last year NIOSH studied the effects of diesel emissions, heat stress, silica exposures, coal dust, radon daughters, welding fumes, asbestos, and hand and arm vibration.

The results of these NIOSH studies are communicated to both employer and employee representatives, and often directly to employees. Similarly, all MSHA and OSHA enforcement efforts and regulatory requirements are communicated equally to employer and employee representatives and made available directly to employees. Most importantly, employer training programs include hazard analysis, communication, and protective techniques. These training programs incorporate many of the findings of the government's's research activities and are, of course, provided to the employees directly.

Although we cannot speak for the federal agencies involved, we can relate to you that our experience demonstrates the agencies have never hesitated to provide pertinent information to employee representatives and, where appropriate, to the employees themselves.

Employees and their representatives are routinely involved in both MSHA and OHSA enforcement activities, inspections and investigations. Similarly, employee representatives are provided the opportunity to accompany NIOSH investigators during site visits and research projects. Further, OSHA, NIOSH and MSHA provide employees and their representatives with notice of their right to participate, and of the results of their enforcement and research projects.

In addition to the extensive communication efforts involved in these programs, it must be emphasized that employee exposures to potentially toxic substances are limited to safe levels by OSHA and MSHA permissible exposure limits. Violation of these exposure limits carries potential civil and criminal penalties. And, the Committee is well aware of the extensive worker compensation and tort liability costs associated with over-exposures to toxic materials.

Not only do employers have a responsibility to protect their employees, they have a financial duty to their shareholders to avoid the potential for extensive liability. As you know, this liability has proven its disastrous financial consequences.

Finally, there is a massive and complex web of state and local "right to know" laws that provide even more hazard information to employees.

The Inappropriate Provisions Of S. 79

Although perhaps well intentioned, many provisions of S. 79 are totally inappropriate. For example the employee notification scheme (the "triggering" mechanism) is the heart of the bill and illustrative of its potential for severe and troubling consequences.

The bill establishes a government notification and employer-paid medical monitoring scheme for worker populations "at risk" of incurring occupational diseases.

The groups to be notified and monitored are defined as those exposed to occupational health hazards "at intensities or for durations comparable" to any single study, animal or human, that demonstrates that acute or chronic health effects may occur. This triggering mechanism is the core of the bill's many problems and is the fatal flaw that makes it totally unworkable.

The definitions apparently were taken from OSHA's hazard communication rules that were intended to provide preventive training regarding potential hazards. They are totally inappropriate for direct notification of individuals that they are at high risk of disease and its proposed corollary of medical surveillance.

Yet, to assure that the drafter's intent is met, the bill requires that an arbitrary minimum of 100,000 persons be notified yearly and sets a goal of a minimum of 300,000.

Although the simplistic nature of the definition, and the arbitrary number of persons to receive notice and medical evaluations may have popular appeal, they are disastrous from the viewpoint of American industry.

Animal Studies

Animal studies are frequently used in screening compounds for possible causation of disease in humans. Such studies, properly carried out and interpreted, may be sufficient to form the basis for OSHA regulatory requirements to inform and train workers potentially exposed to a hazard.

Yet, such a study is totally inappropriate as the basis for sending notices to employees telling them that they are personally at high risk of disease and require medical surveillance. It has repeatedly been demonstrated that animal studies do not necessarily translate to human risks. Species differences and exposure and duration of risks are important factors. In the occupational setting, engineering controls, personal protective equipment, and worker training enable employees to protect themselves and avoid any risk of disease whatever.

By providing for the use of animal studies in defining high risk populations, the provisions of S. 79 confuse hazard communication principles with disease notification and medical surveillance concepts and result in a scientifically and legally unacceptable triggering mechanism.

Inappropriate Use Of Human Studies

It is equally inappropriate to use studies of isolated instances of human illness, which involve high occupational exposures for long time periods, to notify individuals with low exposures, or short durations of exposures, that they are at risk of disease.

The one essential element needed to justify widespread individual notification is true excess risk of disease. A determination to notify individuals personally that they are at excess or high risk of disease must be based on an examination of numerous factors. Many of these factors were set forth in our testimony before this committee in the 99th Congress. They are included in the recommendations of other witnesses and in the report of the NIOSH Board of Scientific Counselers.

Yet, S. 79 totally fails to require such excess risk, and an examination of the factors essential to the determination of whether the excess risk is attributable to the individuals to be notified. The concept of "high risk" embodied in the title is completely lost in the bill's provisions. It fails to incorporate sound industrial hygiene and epidemiological principles, while concurrently requiring the notification of hundred of thousands of persons. A short example will illustrate:

An epidemiological study of silica exposures where employees are exposed to respirable silica dust at many times the allowable regulatory limits would clearly demonstrate that such an exposed population was at significant risk of contracting silicosis. This type of study could appropriately provide the basis for notification of the studied group (assuming the factors described by the Board of Scientific Counselers indicates it is appropriate _and_ beneficial).

S. 79, however, would also require notification of other groups or subgroups of workers, only potentially exposed to silica, that they, too, may be subject to this "high risk" of contracting a disabling disease. The determination that the _group_ studied is at excess risk is exceedingly complex. A determination that _individuals within the group_ studied are at excess risk is almost impossible. The extrapolation to _non-studied individuals_ is wholly without merit and truly impossible.

In mining, almost all production employees are potentially exposed to some form and quantity of silica dust because it is the most common element found in the rock that must be broken and moved to produce mining products. However, the high silica exposures of the employees in the hypothetical illustration have no relationship whatsoever to the potential exposures of the general mining population.

Different mining operations, like different manufacturing processes, result in vastly different types of potential exposures. While it is an established scientific fact that excessive silica exposures can result in disease, both NIOSH studies and MSHA enforcement inspections have clearly demonstrated that almost the entire mining population is well within compliance limits for silica exposures. And, as I'm sure you know, these exposure limits are based on scientific data demonstrating that controlled exposures, at or below tne regulatory limit for an entire working lifetime, will not result in the occurrence of occupational diseases. Yet, the risk posed by silica may, in many operations, warrant hazard training.

However, to notify all current and past miners that they are at "high risk" of contracting disabling silicosis would be factually incorrect, costly, and emotionally distressing to them. S. 79 confuses hazard training concepts with individual risk notification and medical surveillance concepts. S. 79 fails to recognize the necessity for similar exposure prior to engaging in notification and encourages incorrect massive notification by addressing exposures of similar "intensity or duration." In fact, testimony before this committee by union witnessess on February 24, indicates their belief that 1.2 million workers potentially exposed to silica (regardless of true risk) should be notified and provided medical monitoring.

Emotional Distress

Our concern with the potential emotional distress of employees should not be taken lightly. In January 1985 American workers, and the American public in general, were subjected to a wholly unwarranted and misleading report alleging government suppression of evidence that over 200,000 workers were at increased risk of developing workplace induced cancer, lung disease, heart disease and other health problems.

The report, issued by the Public Citizen Health Research Group (Public Citizen), purported to be based solely on documents provided by NIOSH in response to a Freedom of Information Act request by Public Citizen.

In fact, much of the report contained Public Citizen's own speculations as to potential diseases arising from exposure to various workplace agents, even though Public Citizen had no idea of the extent of such exposures.

The nature and scope of the NIOSH studies cited by Public Citizen were not explained in the report. Thus, it was impossible to determine: (1) whether the studies involved workplace exposure measurement or medical surveillance; (2) whether the studies found any excess risk of illness; (3) whether the excess risk of illness, if any, was due to occupational, as opposed to other causes; and (4) whether the studies cited provided any basis for determining individual risk.

Additionally, the Public Citizen report was rife with reporting errors as to the workplace locations, number of workers involved, and whether or not the workplaces were still in operation.

The misleading report, coupled with its wide dissemination in the press, raised unnecessary fears among American workers, including miners, and demonstrates the ethical and moral implications of any notification system. Yet, this report has been credited as the basis for the introduction of S. 79 and the findings in S. 79 appear to be directly related to the Public Citizen press release. To set this record straight, we recommend that you request GAO to review this incident and the appropriateness and validity of the NIOSH information that it was based on.

S. 79's Lack Of Procedural Safeguards

Horror stories of massive, inappropriate notification can be expected to be sanctioned by S. 79. The only solution that the bill presents is that decisions on notifications would be made by a "Risk Assessment Board" and reviewed by the Secretary of Health and Human Services through a short comment and hearing process, with possible appeal to the courts. However, the time frames for notice, comment and public hearing are so short as to preclude meaningful input on highly complex issues. Further, the Board is so small as to preclude scientific experts in the subjects being reviewed, and it is inappropriatly limited to government representatives.

As with all difficult problems there are no easy solutions, and the creation of another board will not in any way substitute for the careful professional judgment that must be used to evaluate the validity of research studies. And, the short-circuiting of formal rulemaking procedures by the provisions of S. 79 makes faulty notification even more likely. Finally, restricting judicial review by imposing difficult and unwarranted review and stay standards, curtails even further the limited rights of affected parties to seek redress through the courts.

To summarize, the notification triggering mechanisms of S. 79 are fatally flawed. They are not based on the existence of a statistically significant excess risk of disease that can be validly extrapolated to the employees to be notified. They are triggered without formal rulemaking procedural safeguards, and court review is restricted inappropriatly.

The Counterproductive Results of S. 79

First, S. 79 requires notification without requiring that it benefit the individual. Many serious diseases resulting from past occupational exposures cannot be treated effectively. Unlike the positive results of our many preventive efforts, tragically, the course of these diseases cannot be altered through intervention. Like many other occupational diseases after the onset of asbestosis, no intervention technique can impact mortality.

As a result, in these types of unfortunate situations, based on long-past, historical exposures, notification is not preventive in nature, and it is counterproductive due to the emotional trauma it will cause.

Second, S. 79 will severely reduce or completely eliminate future industry funding and perhaps even cooperation in occupational health research. If the result of such research serves to increase unnecessarily and significantly the employer's medical costs and to expose the employer to massive litigation, the future of occupational health research is in jeopardy.

The Costs And Impacts of S. 79

Assessing the potential cost of S. 79 is difficult. The bill's direct costs of identification and notification, although potentially excessive, may be minuscule when compared to the increases in health care and insurance costs resulting from unneeded and ineffective medical monitoring, or inappropriate medical intervention.

And, the direct costs of notification and medical monitoring, evaluation and treatment will be far surpassed by the litigation costs that will result from a massive notification program.

First, S. 79's requirements for medical monitoring and evaluation are scientifically inappropriate. We have already described how the triggering mechanism encourages massive, inappropriate notification. The definition of the medical monitoring required to be provided to those receiving notices is not limited to procedures and tests effective in diagnosing or screening for the occupational disease involved. S. 79 totally fails to restrict surveillance to appropriate and effective diagnostic tools. The resulting massive medical costs will be largely wasted, and certainly inappropriate and unnecessary.

A 100 Billion Dollar Program

In 1977, a NIOSH report estimated that a notification and surveillance program for 21 million employees would cost a total of $54 billion or $1 1/2 billion per year. Based on medical cost increases and general inflation, this estimate could easily be doubled for 1987 dollars. As a result, if implemented as permitted by its provisions and envisioned by its supporters, S. 79 could ultimately cost in excess of $100 billion and at least $3 billion annually.

Second, NIOSH has proven that notification of employees entails unjustified liability claims, both within and outside of the workers' compensation system. The potential for such claims may be acceptable when notification is truly justified. However, to encourage unfounded claims, through an inappropriately designed and unneeded notification system, will undoubtedly be a serious threat to the viability and competiveness of American industry.

With Another $112 Billion in Yearly Litigation

A NIOSH pilot notification program in Augusta, Georgia, notified less than 800 individuals and resulted in $300 million in lawsuits. Similarly, this committee is very much aware of the thousands of previously approved black lung claims and the billions of dollars spent on that program even though GAO discovered that only a small percentage of those claims were based on medical evidence. You are also aware of the asbestos litigation crisis and its costs, even though much of this litigation is also unwarranted. To inadvertently encourage a national epidemic of unfounded claims would be devastating.

If the NIOSH pilot program litigation experience is extrapolated to S. 79's goal of a minimum of 300,000 notifications per year, we can expect at least $112 billion in litigation claims in the first year of the program.

We have seen the rapid erosion of our industrial base and the ever-rising spiral of compensation and insurance costs. The survival of what is left of America's basic industries is dependent upon our competitiveness in world markets. Undertaking the program described by S. 79 could place a severe economic strain upon us without any corresponding health gains. We respectfully request that you seek a prospective study of the cost and benefit of S. 79, prior to its enactment, from the General Accounting Office and the Office of Management and Budget. We also request that you seek the assistance of the Justice Department to survey the potential for unnecessary litigation that would be created by the bill.

We believe that S. 79 is both unnecessary and poorly designed. Although we are in complete agreement with the goal of protecting the health and safety of our nation's workforce, we are strenuously opposed to this bill. In contrast, we appreciate Senator Quayles' effort to address the notification issue in a scientifically sound manner. Although we do not believe there is a need for any legislation, we believe that Senator Quayle's efforts demonstrate the total invalidity of S. 79.

We appreciate the opportunity to present the views of our member companies. If we can be of any assistance or provide any further information please contact Henry Chajet, AMC Senior Counsel, at 202/861-2857.

Senator QUAYLE. The next witness will be Dr. Earl Arp, who is Director of Health and Safety for Ashland Oil. He is accompanied by Gerry Raabe.

Mr. Arp?

Mr. ARP. Good morning, Senator. Notwithstanding the absence of nametags, I am Dr. Earl Arp, Director of Health and Safety for the Ashland Oil Corporation. With me today is Dr. Gerry Raabe, Manager of Epidemiology and Medical Information Services at Mobil Oil Corporation. We are here today on behalf of the American Petroleum Institute, API.

We appreciate the opportunity to present API's views on the issue of notifying individuals of health risks from chemical exposures. API and its 200 member companies are committed to employee protection and prevention of occupational disease. We believe employers have a responsibility to educate employees, and we are providing information and training to employees about hazards in the workplace.

There is no doubt that employees have the right to know about the hazards they face or that employers have an obligation to provide a safe work environment. API supports the principle of notification of worker populations that is based on valid scientific evidence and that provides usable information.

However, given the complexities involved and the state of the scientific evidence, we have not yet seen a legislative approach that would be both sound and workable.

Notices to individuals could, in fact, do more harm than good if they are erroneous, do not explain relative risks, contributing health factors or scientific uncertainties. The goals of any legislation should be accurate assessment of risks, useful communication of risk-related information, and improvement of worker health through preventive measures.

We do not believe that Senator Metzenbaum's bill would achieve these goals.

Our specific concerns are these. The Risk Assessment Board would not be required to evaluate all the relevant peer reviewed scientific evidence before assigning risk to individuals. Notification could be based on only one study showing risk, while others, showing little or no risk, could be ignored. Moreover, accurate assessment of risks requires knowledge of past exposure conditions and, unfortunately, that knowledge often does not exist.

The Board would be required to notify a minimum of 100,000 people per year and to aim for 300,000 people per year. Establishment of such arbitrary quotas is unsound. It transforms the scientific evaluation into a numbers game. Even worse, it predetermines the extent of the problem before all the evidence is in.

The public would have only 45 days to comment upon the Board's findings, and the Board would then have the same short period to evaluate comments received and issue a final decision. This is simply not enough time to review the volume of data likely to be generated.

Your bill, S. 638, avoids some of these shortcomings. It provides some criteria for weighing the scientific evidence. It sets no quotas. And it requires that the benefits of notification be evaluated. These improvements would make a critical difference in the quality of the scientific decisions that would be made under this proposal.

However, we do have several concerns with S. 638. The bill does not limit notification to occupational populations. Communities may also have to be notified. Generally, studies done on community populations have not been designed to test causal associations. They do not provide sufficient information upon which to base notification.

Moreover, this kind of notification is not necessary because the citizens will have access to health risk information under the Superfund Amendments and other environmental statutes.

The bill states that the study methods must be evaluated, but does not say how. Specific criteria, such as the NIOSH guidelines for how a study should be designed and analyzed, are needed to ensure that the studies are valid. Senator Metzenbaum's bill is worse on this point; it does not even require study methods to be evaluated.

In summary, API has serious concerns about both of these bills, particularly S. 79. Their objectives, though worthwhile, are not achievable. Valid risk assessment which relies on such data is exceedingly complex, and translating these data into information that individuals can understand and use is a monumental task.

For these reasons, we are concerned that notification may not be based on sound evidence and will not provide usable information to individuals, and will not prevent disease—the most important objective of all.

API's detailed comments on both bills are contained in our written statement submitted for the record. Dr. Rabbe and I will be pleased to respond to questions at the appropriate time.

[The prepared statement of Dr. Arp follows:]

STATEMENT OF THE
AMERICAN PETROLEUM INSTITUTE
ON SENATE BILL NO. 79
"HIGH RISK OCCUPATIONAL DISEASE NOTIFICATION AND PREVENTION ACT OF 1987"

Subcommittee on Labor
U. S. Senate Committee on Labor and Human Resources
March 9, 1987

The American Petroleum Institute (API) appreciates the opportunity to present its views with regard to Senate Bill No. 79, the "High Risk Occupational Disease Notification and Prevention Act of 1987." API is a national trade association comprised of corporate and individual members engaged in all facets of the petroleum industry. API appreciates the opportunity to address the issues raised by S. 79, because we believe there are some significant problems in the bill as currently drafted.

The generation of relevant and reliable information with regard to potential occupational health risks caused by exposures to hazardous materials is a matter of major concern to the petroleum industry. API and its members have and will continue to conduct research into the possible health effects of the chemical substances used in the processing and manufacturing of petroleum products to ascertain whether there are significant occupational health risks which should be addressed to provide workers a safe and healthful workplace.

API also believes that where human health effects studies disclose evidence that groups of workers are being or have been exposed to materials which present a significant occupational health risk, such persons should be informed of the results of the studies. Further, many API member companies already have a policy of informing employees of the outcome of any studies, regardless of whether adverse human health effects are observed. Finally, most employees are already covered by the OSHA Hazard Communication standard, which provides training and information regarding hazardous substances in the workplace.

Given the mandatory and voluntary efforts, API has serious reservations whether the goal of notifying the members of a study cohort is served by a massive new federal notification program. These concerns escalate even further when API envisions S. 79 as the vehicle for this new notification program.

Deciding whether a particular epidemiological study demonstrates the existence of an occupational health hazard is a complex and difficult undertaking. Even if a risk is determined to exist, identifying the appropriate persons to be notified is an issue which requires sound scientific evidence accompanied by good professional judgment. Unfortunately, at every key "crossroad," S. 79 contains critical flaws which: (1) prevent the development of necessary analyses and data to resolve these difficult questions of risk; and (2) constrain the exercise of the professional judgment of the "experts" it would assign this complex task.

Moreover, the bill fails to recognize and reflect the fact that there are severe limitations in the ability to screen for certain types of severe or fatal diseases and/or to provide exposed persons with an effective medical treatment for the disease. These limitations take on special significance because S.79, as API demonstrates in this statement, will in many instances result in the notification of persons who are not at risk of disease due to occupational exposures. The bias toward notification is inherent in the procedures and provisions of the bill. Accordingly, persons who are not actually at risk due to occupational exposures will be erroneously told that they suffered harmful exposures. Moreover, due to the current limitations of medical science, they may also be told that there is nothing that can be done to assist them. Such news can only have devastating results and, in itself, could cause far more problems than it solves.

API believes that more analysis of the possible negative impact of notification should be conducted before enacting legislation, especially as sweeping as S.79. As API discusses in this statement, there are meritorious provisions in a substitute bill sponsored by Senator Quayle of Indiana. However, certain revisions and more specificity are needed before this legislation could be enacted.

At a minimum, though, API believes several important attributes are needed in any notification legislation:

1. It must ensure that any determinations of risk are based upon scientifically valid and relevant human health effects studies by carefully analyzing study design, results, and methodologies;
2. It must ensure that the risks which are found to constitute an "occupational health hazard" are indeed attributable to such exposures;
3. It must differentiate between persons who were subjected to exposures identified in a particular study and those who may have been exposed to similar substances or processes, but at different levels of intensity and duration;
4. It should require that notification, especially if on an individual basis, communicate the real nature of the risk, including the uncertainties and confounding health factors potentially affecting the risk;
5. It should provide that the decision to notify takes into account the availability of medical monitoring and intervention techniques and is sufficiently scientifically sound to avoid making unnecessary notifications which could cause potentially harmful public alarm;
6. It should ensure that the procedures by which any person(s) will make these evaluation and notification decisions, provide adequate time to develop and consider all relevant data and evidence, and that the decisions are subjected to a review which is procedurally fair and substantively meaningful; and
7. It must prevent the federal government from attempting to impose its notification or related responsibilities on private parties, unless such duties are assumed on a wholly voluntary basis.

API believes S.79 fails to meet adequately any of these basic requirements. It should not be adopted into law.

I. THE BILL FAILS TO IDENTIFY SUFFICIENT AND APPROPRIATE CRITERIA FOR DETERMINING WHETHER NOTIFICATION IS NECESSARY

A. There Are Inadequate Safeguards To Ensure an Occupational Health Risk Exists

S. 79 defines an "occupational health hazard" as a "chemical, a physical, or a biological agent, or an industrial or commercial process, found in the workplace for which there is statistically significant evidence (based on at least one study conducted in accordance with established scientific principles) that acute or chronic health effects may occur in exposed employees." § 3(7). Although the definition requires that studies be conducted in accordance with "established scientific principles," there are neither guidelines for conducting this review nor specific requirements that the Risk Assessment Board (Board) 1/ make such a determination before proceeding to identify a population at risk. Hence, the apparent "safeguard" may be largely illusory.

API maintains that an orderly review procedure necessitates a specific finding by the Board that the study or studies establish the existence of a scientifically valid occupational health risk. In addition, API believes that such risk determinations should be triggered by the results of human epidemiological studies. Animal studies, alone, should

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1/ S. 79 would establish a 5 member Risk Assessment Board within the Department of Health and Human Services to make the determination of whether a population was at risk of disease and the manner by which members of the "population" would be notified. See Section 4.

not serve as the basis for concluding that a worker population should be notified; these studies are best used to support the findings of human epidemiological studies.

Assuming that a particular epidemiological study indicates the possible existence of an occupational health risk, there must be a systematic review of the study to ensure its validity and relevance. API suggests that the guidelines recently developed for the National Institute for Occupational Safety and Health (NIOSH) by its Board of Scientific Counselors 2/ may provide an appropriate framework for making this determination. However, as the NIOSH report recognizes, these are merely guidelines rather than "hard and fast" rules and should not be rigidly applied in all cases; nor do they constitute the total of all guidelines which might be applicable. 3/ The "case-by-case" nature of the process requires that a flexible approach be employed.

The first step in this process would entail a determination that the study is appropriately designed. To

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2/ See "Report of the Subcommittee on Individual Worker Notification NIOSH Board of Scientific Counselors," February 15, 1986.

3/ As the Report states: "These guidelines are meant to be flexible and applied on a case-by-case basis. We must stress that these recommendations are meant to be guidelines; they are not to supplant scientific interpretation and judgment. The cohort studies under consideration are complex and we consider it inappropriate to apply simple, rigid rules to complex studies." Report at p. 5.

this end, the Risk Assessment Board (or another group of experts) would review:

(1) whether the study hypothesis was appropriate;

(2) whether the study size is sufficient to address the hypothesis; and

(3) whether the subject selection was well-documented and unbiased.

The Board would, next, review the adequacy of the methods and data used in conducting the study, evaluating, for example, such factors as the following in the case of an occupational cohort study:

(1) whether there was adequate follow-up of the cohort;

(2) whether the disease outcomes or measures of morbidity were adequately documented;

(3) whether sound statistical methods were employed; and

(4) whether the study employed reliable risk estimates with appropriate statistical confidence intervals.

Finally, the Board would evaluate the study to ensure its findings are sufficient to conclude there is evidence that a particular substance or activity constitutes an "occupational health hazard." API believes that the "statistical significance" provision in S. 79 is inadequate. Statistical significance is only a minimum requirement and the following additional factors should also be considered:

(1) whether it is consistent with other human studies, animal studies, known mechanisms of action and metabolism to substances having similar activities;

(2) whether there is biological plausibility;

(3) whether the strength of association is adequate; and

(4) whether dose-response relationships exist.

All of this evaluation should precede any determination of whether there is a "population at risk." At present, S. 79 would not require a study to undergo such validation. Instead, such issues could only be raised during the extremely short comment period allowed to the public. There is no requirement that the Board undertake such a review prior to issuing a "notice of proposed determination." Nor is it required to be addressed in the text of the notice of proposed determination. 4/

The clear inference to be drawn from the bill is that the adequacy of the evidence purporting to establish an "occupational health hazard" is not to be addressed in anyway other than in a cursory fashion. This is particularly alarming because the bill allows the finding of an occupational health hazard on the basis of only one study.

API submits that the failure of S. 79 to provide a systematic means for establishing the validity of studies which could serve as the basis for a "hazard" determination, is a major and fatal flaw. When it is coupled with the other

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4/ See § 4(c). In fact, there is no requirement to ever find that the study itself is valid. At best, the "notice of proposed determination" merely contains a "concise statement" of the basis for including particular persons within the population at risk. § 4(c)(2)(B).

deficiencies evident in the bill, 5/ S. 79 can be seen as sacrificing sound scientific principles for expedient notification.

Such a trade-off guarantees that there will be many "false positives" whereby the risk actually posed by the substance or activity falls is not associated with a bona fide health hazard. This will not be corrected by subsequent proceedings before the Board. Nor will the courts have any authority to rectify the deficiency.

API submits that any notification legislation must contain specific provisions to ensure an adequate and accurate factual record exists and supports a finding that a particular hazardous substance, process, or practice constitutes an occupational health hazard. The recent substitute bill drafted by Senator Quayle of Indiana makes an effort to address these fundamental requirements. Unfortunately, S. 79 does not meet this basic requirement.

B. The Criteria for Determining the Population at Risk Should Include the Use of Attributable Risk

After it has been determined that a study meets the requisite validation criteria, the next concern should be whether all members of the study cohort were at risk and whether they have been notified. Since these persons were

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5/ These deficiencies are discussed in detail in the subsequent portions of this statement.

exposed to the potential occupational health hazard, they are the principal and most immediate "population" of concern.

However, to identify the appropriate "population at risk" the inquiry should include an analysis of the nature or degree of the risk of contracting a disease due to the study participants' occupational exposures. API believes that an appropriate approach for assessing risk for employee populations would be to include the concept of "attributable risk" within the factors considered by the Board.

Here risk is examined to determine the "fraction" or proportion of the disease among the exposed that is related to the exposure of interest. This attributable proportion is distinct from the relative risk where the ratio of the incidence of disease in exposed and unexposed populations is calculated. Attributable risk conveys a sense of how much of the disease in an exposed population can be prevented by eliminating the occupational exposure.

For the most part epidemiology is observational in nature rather than experimental. To truly establish the "cause and effect" of some substance, one needs to experimentally produce the hypothesized outcome using the putative substance. Ethically we are prevented from conducting human experimentation; consequently we resort to using animal models for the experimental induction of disease and then extrapolate the results to man, with varying degrees of success. In lieu of sometimes questionable animal data, epidemiologists must rely on observational data from which they may draw causal inferences. However, that inference is based on association; an association which has for the most part been validated statistically but not experimentally. Because the causal inference is based on association rather than on experimental proof, replicate observational data are mandatory to rule out the possibility that the observed effects did not occur merely by chance. Even experimental proof requires more than one replicate to rule out chance or artifact.

There are few instances in modern occupational epidemiology where an exposure factor has been pathognomonic for a particular disease. Those causal associations are asbestos and mesothelioma, vinyl chloride and angiosarcoma of the liver, and finally, radium and osteogenic sarcoma. The fact that the three diseases mentioned are not only relatively rare but also exhibited pronounced increases in their respective incidences among the involved occupational groups, aided epidemiologists in establishing causal associations. For the majority of occupational diseases however, multiple causes rather than unitary etiologies are probably operative.

The use of "attributable risk" is an important means of ensuring that the bill, which is premised upon potentially harmful occupational exposures, remains consistent with its findings and purpose. Its exclusion from the bill seriously undermines the scientific accuracy of the process.

C. The Determination of Population at Risk Should Not Be Expanded beyond the Original Members of the Study Cohort

The impact of S. 79, is potentially far-reaching because the bill does not confine the identification of the "population at risk" to the participants in the study or studies relied upon by the Board. It is not clear that the drafters of the legislation recognize that expanding the notification effort beyond the original members of the study cohort will involve an enormous amount of time and effort. Certainly it is not reflected in the time allotted to the Board in making its determinations.

In essence it will require carrying out an almost complete cohort study including identifying all persons who may have been exposed to a chemical, process, or job, determining and reviewing the person's complete work history to determine if he/she was exposed at similar intensities and duration, and following up the cohort to determine its current status. 6/

API maintains there must be credible evidence that the "population" was subject to exposures of a comparable intensity level and duration as those encountered by the study group. S. 79 would only require comparable intensity or

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6/ This information is rarely computerized. It will have to be gathered from hard copy records by hand and is typically the part of an epidemiology study that takes from one to three years to complete. Because it is labor intensive, it is very expensive in both in terms of manpower and money.

duration. Making this determination will require a considerable amount of factual information. Any persons charged with determining a "population at risk" should be required to consider factors such as: (1) whether current exposures are similar to previous exposures; (2) whether changes in production process controls or the substitution of other materials have affected the likely exposures; (3) whether there are differences in the levels of risk among sub-populations of potentially exposed workers; and (4) the relative and absolute time periods for which the risks were present.

API believes it would be preferable to require only that the original members of the study cohort be subject to the determination of the "population at risk." To the extent that this concept is expanded beyond the study cohort, there must be specific requirements and the time to meet fulfill them, to ensure the integrity of the evaluation.

D. The Bill Diminishes the Importance of the Availability of Medical Monitoring and Intervention by Separating It from the Determination of Population at Risk

S. 79 removes certain relevant factors from the procedure by which the Board would identify the "population at risk." Instead, these factors are placed in the designation of identified populations for notification. See Section 4 (b) (3). For example, API agrees that a key consideration in determining whether persons should be notified is the availability of medical monitoring and intervention techniques. 7/ API also agrees that it is appropriate to notify persons at risk who are most likely to benefit from medical surveillance and medical counseling. However, these factors should be considered in determining the population at risk, not merely in prioritizing the notifications.

In addition, API strongly disagrees with the bill's emphasis on notifying persons with exposures for which there exists a permanent standard promulgated under Section 6 (b) (5) of the Occupational Safety and Health Act (OSH Act). These workers are perhaps the best protected among all employees since the standards adopted are required to ensure:

> no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.

29 U.S.C. 655 (b) (5). Furthermore, they are already subject to medical monitoring requirements.

The notification criteria should not be separated from the determination of the population at risk. In doing so, the bill raises the concern of whether the availability of medical monitoring and intervention will be adequately considered. The bill should also not put such a heavy focus on the Section 6 (b) (5) OSHA standards.

7/ API notes that the substitute bill sponsored by Senator Quayle includes this consideration in preparing notification guidelines.

E. The Minimum Notification and Target Notification Numbers Must Be Eliminated from the Bill

One of the most significant provisions of S. 79 which casts doubt upon the scientific credibility of the entire notification process is contained in Section 4(b)(3)(c):

> The Board shall notify or coordinate the notification of not less than 100,000 employees per year. The Board shall make every reasonable effort to notify or coordinate notification of not less than 300,000 employees per year.

The requirement that at least 100,000 employees be notified each year is wholly inconsistent with an informed and impartial evaluation of scientific evidence regarding the workers who may have encountered comparable exposures to those of a study cohort. The 300,000 employee target number is even more problematic.

API categorically opposes the use of such minimum notification requirements and yearly targets. The determination of a population at risk must remain scientific and objective.

II. THE PROCEDURES TO BE EMPLOYED BY THE RISK ASSESSMENT BOARD WILL PREVENT RATHER THAN ENCOURAGE DEVELOPMENT OF A FULL FACTUAL RECORD

A. The Bill Contains Impossibly Short Time Frames

The procedures which S. 79 would apply to the Board's determination of a population at risk will seriously jeopardize a full disclosure of relevant factual materials and severely constrain the Board from utilizing its professional expertise. As mentioned earlier, the "notice of proposed determination," although published in the Federal Register, is not required to state with any degree of detail, the basis for determining that an occupational health hazard exists or why particular classes or categories of employees are deemed to be "at risk." There is not even a requirement that the studies relied upon by the Board in proposing a determination, will be made readily available for review by interested parties. 8/

Another major shortcoming of the "procedures" involve the extremely short time periods both for the submission of public comments and the issuance of a final determination by the Board. The public is allotted a scant 45 day comment period. This is hardly sufficient time to obtain and review the study or studies, evaluate the proposed "population at risk," and prepare meaningful comments. Moreover, it is too short to develop any original material or data pertinent to the proposed determination.

The Board's time frame is even more onerous. Given that it must review the entire record, it will find it a near impossibility to issue a determination within 45 days after the termination of the hearing prescribed in Section 4 (c) (2) (D). Moreover, the authority to extend the time frame, in Section 4 (c) (4), is wholly illusory since, at best, this

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8/ This is particularly onerous given the extremely short comment period.

gives the Board a maximum of 60 days, assuming the hearing can be completed prior to the end of the public comment period. It is more likely that the "extension" will provide the Board a very limited amount of additional time. And, if the Board misses this time deadline, it faces a potential civil action for mandamus.

These time frames are simply unrealistic and unnecessary. They cannot be justified by a need to apprise workers of serious health risks. Many statutes include special provisions to address "emergency" circumstances -- there are no such provisions in S. 79.

The public comment and Board review provisions in S. 79 reveal the process to be one of form rather than substance. Any legislation adopted must provide adequate time to develop and review relevant factual data.

B. The Hearing Should Be Explicitly Made "On the Record" and Include Opportunities To Present Relevant Evidence

Traditionally, any statute which called for an adjudication, such as the one required of the Board -- "on the record after the opportunity for a public hearing" -- meant that the parties would be afforded an opportunity for a fact-finding hearing like that prescribed in 5 U.S.C. §§ 556-557 (Administrative Procedure Act). S. 79, despite the use of very similar words, provides no opportunity to present oral or documentary evidence, to submit rebuttal evidence, and to conduct cross-examination as may be required for a full and true disclosure of the facts. See 5 U.S.C. § 556(d).

API maintains that the factual nature of the determination which the Board must make necessitates the opportunity to develop a full and complete record. This can only be accomplished when there is adequate time to develop the facts and an interactive process between the participants in the hearing and the Board.

Accordingly, any legislation adopted should provide the Board with explicit authority to allow the submission of oral and written evidence, rebuttal submissions, or the examination of witnesses whenever it finds it necessary to either resolve issues of material fact or to achieve a full and fair disclosure of all facts. By placing this in the discretion of the Board, there will be the requisite safeguards to prevent protracted and unnecessary proceedings. More importantly, though, the Board will have access to information which will allow it to make informed decisions.

C. S. 79 Provides an Unrealistic and Inappropriate Standard for Judicial Review

Although there are provisions for seeking judicial review of the Board's decision, they are severely constrained by standard of review specified in the legislation. For example, by eliminating the "substantial evidence" review standard the legislation departs from Section 706 of the

Administrative Procedure Act (APA) 9/ and the scope of review previously identified by Congress in protecting employees from occupational health risks. See Occupational Safety and Health Act, Section 6 (f), 29 U.S.C. 655 (f).

The nature of the Board's decision necessitates a standard of review, like the substantial evidence test, which evaluates the adequacy of the evidence. As Judge Weinstein noted in his landmark decision regarding Agent Orange exposure:

> ... careful scrutiny of proposed evidence is especially appropriate in the toxic tort area. The uncertainty of the evidence in such cases, dependent as it is upon speculative scientific hypotheses and epidemiological studies, creates a special need for robust screening of experts and gatekeeping under Rules 403 and 703 [Rules of Federal Evidence] by the court. 10/

9/ In addition, several other traditional review standards contained in Section 706 of the APA are eliminated, e.g. "or otherwise not in accordance with law," "or short of statutory right," and "due account shall be taken of the rule of prejudicial error."

10/ Rule 403 of the Rules of Federal Evidence regards the perogative of a judge to exclude evidence whose probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, misleading the jury, or undue delay. API believes that the Board should have such authority to refuse to receive evidence if it would lead to prejudice or undue delay. Rule 703 addresses the bases of opinion testimony by experts and allows a judge to consider in deciding whether to admit such opinions if they are based upon facts or data of a type reasonably relied upon by experts in the particular field. This too, is an important authority which the Board should be able to employ in weighing evidence received during the proceedings, although not necessarily in accordance with the federal evidentiary standards.

In Re Agent Orange Product Liability Litigation, 611 F. Supp. 1223, 1260 (D.C.N.Y. 1985). API is not arguing that the Federal Rules of Evidence should be applied to the proceeding before the Board. Nor are we contending that it should be as rigorous as a trial type proceeding. However, the procedure must allow sufficient and substantial evidence to be adduced for sound decisionmaking. Therefore, the review of the Board's decision by a court should employ the substantial evidence review standard.

D. The Composition of the Risk Assessment Board Should Be Revised To Ensure Greater Expertise

S. 79 would establish the Risk Assessment Board within the Department of Health and Human Services. The Board would consist of 5 members appointed from the Public Health Service of the following disciplines: epidemiologist, toxicologist, industrial hygienist, physician, and occupational health nurse. The Board would also be provided with a full-time staff.

API believes that an expansion of the membership of the Board from 5 to 9 members would serve two very useful purposes: (1) it would strengthen the expertise of the Board in three critical areas; and (2) allow persons from outside the Public Health Service to participate in the work of the Board.

First, given the types of studies likely to be reviewed by the Board, it would be advantageous to appoint two rather than one epidemiologist. As discussed earlier, API believes that the determination of populations at risk should be based upon human epidemiology data. Accordingly, to ensure that such studies are subjected to a thorough and impartial scrutiny, it is important to increase the number of epidemiologists on the Board.

Similarly, since the determination of the population at risk will involve an evaluation of whether there are workers which have had comparable exposures to the cohort of the epidemiological studies, it would be prudent to appoint two rather one industrial hygienist to the Board. Persons with these backgrounds would be familiar with different job classifications and the related types of exposures. Again, there is a significant benefit in assuring that there is a constructive and informed base of expertise in this important area.

API also believes that an occupational health physician should be added to the Board in addition to the "physician" already identified in S. 79. Since the potential identification and treatment of possible occupational-related disease is the focus of the legislation, at least one physician should have specific experience and expertise in such diseases.

Second, while it is appropriate to use a "core group" of persons from the Public Health Service, API believes that only 4 members of a nine member committee should be from the Service. At least an additional four members of the Board should be selected from outside the Public Health Service and include experts reflecting the viewpoints of industry and labor. The goal here is to ensure that the Board contains the experience and perspective of those interests likely to be affected by any notification decisions. To ensure the selection of these persons achieves a balance of viewpoints, the appointments should come from the National Academy of Science, an organization known for its credibility and impartiality. The ninth member of the Board should be the Assistant Secretary of Health to ensure that the Board functions in a manner which is consistent with the other branches of Health and Human Services.

In summary, API recommends the following be the composition of the Board: 2 Epidemiologists, 1 Toxicologist, 2 Industrial Hygienists, 1 Physician, 1 Occupational Physician, and 1 Occupational Heath Nurse. Four of these persons would come from the Public Health Service and four would be appointed by the National Academy of Sciences representing a balance of industry and labor viewpoints. The ninth member of the Board would be the Assistant Secretary of Health, Health and Human Services.

III. THE METHOD AND CONTENTS OF THE NOTIFICATION ARE POORLY DESIGNED AND LIKELY TO PROVE IMPRACTICAL AND COSTLY

A. Individual Notifications Should Be Selectively Employed

API has discussed previously that it is categorically opposed to any provision which sets minimum worker notification floor or yearly notification target numbers. Such "quotas" are wholly inconsistent with an objective, scientifically sound review of available evidence to determine populations at risk.

Moreover, like other provisions of the bill, they reflect a general insensitivity to the importance of ensuring that individuals be notified only when they can be provided a real understanding of the possible risks to which they may have been exposed. Absent from the bill's requirements are provisions requiring notification to apprise individuals of confounding health factors, scientific uncertainties regarding the possible risk, and the relative risks. Accordingly, the bill will fail to provide individuals with the requisite information to understand the real health risks they may have experienced due to occupational exposures to hazardous substances.

As mentioned earlier, use of attributable risk assessment techniques would be a means of generating more accurate risk-related information. Other information related to disease prevention would also be useful to the individual. However, any notification which fails to responsibly describe the nature of the risks to individuals cannot be assumed to be superior to other more generic notification techniques or to no notice at all.

To provide the program with some general notification guidelines, API first suggests that individual notification be the preferred method only for the members of the cohort studied which have been specifically identified as being at risk. As a second general rule, if there is a need to, employees identified with similar intensities and durations of exposure comparable to the cohort studied would be notified using the most feasible alternative.

S. 79 is rather limited in its consideration of possible alternatives to individual notification. The only real alternative contemplated is the use of public service announcements. See Section 6 (c) (2). There may be other types of publications, organizations and resources which would lend themselves to a broad dissemination of information. These should be investigated and utilized to disseminate more useful information and to avoid the potentially high costs of individual notification.

B. The Current Legislation Will Encourage the Government To Shift the Duty To Notify to Employers

API supports provisions allowing employers to seek the authority to notify workers which are determined to be in a population at risk. Such cooperative efforts could be integrated into existing programs which employers are utilizing to notify workers of potential occupational health hazards.

However, the emphasis of S. 79 on individual notification, to the exclusion of other more feasible and effective alternatives, runs the risk of discouraging cooperative efforts which would benefit the worker and save the resources of the federal government. Since the notification costs for all members of a particular population at risk are not likely to be uniform, there will be an incentive for the government to shift the responsibility for conducting the more expensive notifications to another party. API is concerned that the certification program could become the avenue for such action. For example, were an employer to seek official certification to notify current employees, approval could be withheld until the employer agreed to notify past employees.

Of more concern, though, is the possibility that the government would attempt to use its grant of regulatory authority in Section 13 of S. 79, 11/ to prescribe regulations which place burdens on employers to search records or to

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11/ Section 13 provides: "The Secretary shall prescribe such regulations as may be necessary to carry out this Act." This overly broad grant of authority could be used in an abusive fashion.

provide names and addresses of current and former employees. 12/ Although the bill specifically allows the Secretary of Health and Human Service access to information as already provided for in the OSH Act, Federal Mine Safety and Health Act, and the regulations promulgated under the Acts, the implementation of S. 79 is likely to become so onerous for the government that measures to compel private party action may be employed as an expedient means for limiting the high governmental expenditures. The requirements of S. 79 should be reevaluated both as they affect the federal government and employers in the public and private sector.

API believes that by providing greater flexibility to the federal government and public and private employers to use a variety of notification devices, such problems may be minimized. However, to the extent that employers participate in the program, their involvement must remain voluntary. Accordingly, notification legislation without adequate safeguards to prevent the abuses discussed above should not be adopted. Such legislation is clearly inconsistent with its own "findings and purpose." See Section 2.

12/ API has previously discussed in this statement the enormous burden attendant to determining whether persons in addition to the study participants are part of the "population at risk." See API Statement at p. 10.

IV. THE PROPOSED LEGISLATION FAILS TO REFLECT AN UNDERSTANDING OF THE ROLE OF MEDICAL MONITORING IN A NOTIFICATION AND COUNSELING PROGRAM

The role of medical monitoring is touched upon in three sections of S. 79. First, in designating a population at risk the Board is to undertake as its "first priority" to designate populations likely to benefit from medical surveillance or health counseling. Section 4 (b) (3) (A). Second, S. 79 requires that the contents of a worker notification include counseling information appropriate to the nature of the risk, including the advisability of initiating a personal medical monitoring program and the most appropriate type of medical monitoring for the disease associated with the risk. Section 5 (b) (4). Finally, the bill provides that any employee notified shall be provided by his current employer with the testing, evaluation, and medical monitoring recommended as a result of an exposure to an occupational health hazard. Section 9 (a). 13/

All of these provisions, though, appear to presume that there are reliable screening tests to identify the particular disease(s) and medical intervention techniques which can alter or affect the course of the disease.

13/ The costs of such testing, evaluation, or monitoring shall be borne by the employer if any part of the exposure took place during the course of the employee's employment by the employer. Otherwise the employer can charge the employee at the cost to the employer.

Unfortunately, neither are available for many types of diseases.

The goal of any responsible notification program should be apprising workers of information which will secure for them a tangible benefit. It should not be a conduit for spreading fear or false concerns.

API believes that disease prevention must remain the principal goal of any occupational health program, including a notification program. Where the deliberations of the Risk Assessment Board or any other group of experts identify risks which can be addressed through programs of prevention, they serve a useful purpose. Similarly, where there are effective screening techniques to allow the early detection of disease and the requisite medical intervention techniques to address the problems, medical surveillance programs provide a tangible benefit to the worker.

S. 79, though lacks this sharp focus, and appears destined to be swept into a process whereby persons are notified but given no specific answers or useful advice. This will prove disasterous if, as API has demonstrated, the bill will result in notifications to workers whose risk of disease is either conjectural or nonexistent. In addition, to the extent that the efforts of the Risk Assessment Board, the government, and private employers are taken up with notifying persons who have little to benefit from the notification, it will be at the cost of identifying other persons who indeed could have been assisted had the program been properly designed and implemented.

V. NOTIFICATION LEGISLATION SHOULD ATTEMPT TO MINIMIZE LEGAL AND ECONOMIC IMPACTS

A. S. 79 Will Encourage the Filing of Lawsuits

Notwithstanding the limited protection afforded by Section 10 (g), S. 79 will encourage workers and their families to file lawsuits against the government and private employers with regard to the notifications they received and the substances and processes to which they were exposed. Many of these plaintiffs will not allege that they contracted a disease, instead they will attempt to recover for the "fear" that a disease will be manifested in the future.

In other instances, for example where medical intervention techniques do not exist, lawsuits may be filed out of anger or frustration. The stress that the person notified or family members may experience under the expectation that a disease may become manifest, could trigger health problems.

S. 79 will also engender many new lawsuits associated with the "benefit reduction" issue. Employers will be forced to defend and explain normal work transfer decisions, or employees will seek to compel transfers to different work assignments.

B. The Economic Impact of the Bill Has Not Been Adequately Considered

S. 79 is likely to be a very expensive bill to implement. NIOSH has estimated that it could cost up to $ 40 to notify each current employee. Locating and notifying former employees, assuming that tracing evidence is even available, could cost $ 150 per employee. Since epidemiological studies are performed retrospectively, it is reasonable to assume that the mix of worker notification will be 50 % current employees and 50 % former employees. Notifying the minimum number of employees called for in the bill, 100,000, would cost $ 9.5 million per year. If the proposed target of 300,000 employees per year were reached, the notification costs could be as high as $ 28.5 million.

S. 79 also requires that testing, evaluation, and medical monitoring be provided each employee notified as being at risk. It is likely to cost at least $ 500 per examination to cover the expense of time taken off from the job, transportation costs, the costs of the examination, and laboratory testing. If only two-third of the target number of 300,000 employees per year were subject to such procedures, the cost would be $ 100 million per year. To the extent that a large percentage of these workers were "false positives" because of erroneous notification criteria, the wasted costs could entail a substantial amount of resources.

These costs will not be borne alone by particular individuals, the federal government or corporations. They are most like to be recovered through private and governmental medical insurance programs. Ultimately, this will increase premium costs for all citizens.

API believes the potentially high costs attendant to a notification program require Congress to use care in its planning and development. Legislation must attempt to confine notification to those persons truly at risk. As currently drafted, S. 79 will not achieve this goal.

VI. SUBSTITUTE LEGISLATION SPONSORED BY SENATOR QUAYLE IS A MARKED IMPROVEMENT OVER S.79

A. The Substitute Legislation Contains Several Important New Factors and Safeguards

API believes that S.79 should not be adopted in its present form. In addition, as the foregoing statement demonstrates, there are so many deficiencies inherent in the bill that it is questionable whether it could ever be turned into a plausible piece of legislation.

Accordingly, API believes substitute legislation should be considered as an alternative to S.79. Senator Quayle of Indiana has drafted such substitute legislation and API finds that it has many attributes which are a significant improvement over S.79.

The principal focus of the Quayle substitute concerns the disclosure of the results of "risk studies" conducted or supported by the Department of Health and Human Services (HHS). The bill would require the Secretary to promulgate standards governing the disclosure of information from "risk studies" concerning "significant risks" to the health of individuals who were exposed to hazardous substances and physical agents and who did not give informed consent to such studies. These standards would be developed by the Secretary, in consultation with the Director of the National Institutes of Health and Director of the Centers for Disease Control and would address the provision of notice to study subjects and nonstudied individuals.

API supports the decision to concentrate on government sponsored studies. In the past, the lack of a consistent set of guidelines for informing the participants of such government studies has raised speculative concerns about the commitment of HHS and other agencies to apprise persons of potentially significant health risks. API hoped that the guidelines adopted by NIOSH would have allayed many of these occupational concerns. Nonetheless, API believes that to the extent that federal legislation in this area is justified, it is only necessary as it pertains to studies conducted by or for the federal government. As discussed earlier in the statement, the results of studies conducted by companies in the petroleum industry are, as well as other industries, already supplied to company employees and, as feasible, former employees (particularly retired employees). 14/

API is still reviewing the latest version of the Quayle substitute. We would appreciate the opportunity to supplement this statement with additional observations after a more thorough review of the bill. However, some of the bill's provisions which API would support include:

1. The factors to be considered for study subjects --

Many of the factors missing from S.79 are included in the Quayle substitute. In particular, these include the "medical benefits and other consequences to such subjects which may result from the provision of notice," and "the potential effects of failing to provide notice and of providing incorrect notice to such subjects." The importance of these two factors is discussed in substantial detail in the API statement. In short, notification should be a device to communicate in an effective, meaningful fashion the potential health risks and to identify specific actions which will secure tangible benefits for the person exposed to a hazardous substance or agent. It is imperative, therefore, that the process correctly identify the magnitude of the health risk and avoid erroneous notifications which could cause subjects

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14/ Many companies attempt to identify former employees particularly when health benefits would accrue to the persons if notified.

to suffer unnecessary alarm, and perhaps more serious consequences.

Two points, though, should be made more explicit in the legislation. First, API believes that the factors considered by the Secretary in promulgating standards should include the risk attributable to the occupational exposure to the hazardous substance as well as the risk attributable to other sources of exposure. Although this may not be possible in every instance, this information could prove extremely useful to the individual in controlling any future exposures and may be helpful in dealing with medical intervention procedures.

Second, the bill should require that only studies with "statistically significant" results be considered as necessitating notice. API notes that the bill includes in the factors, the "reliability of information" and "soundness of the methodology" obtained or used in the risk study. However, it is appropriate to specifically include "statistical significance" in the factors.

2. Factors to be considered for nonstudied individuals --

API strongly endorses the differentiation of study subjects from nonstudied individuals. Applying the results of a risk study beyond the study subjects requires a careful consideration of exposure factors and other factors often specific to particular industries and job categories.

API describes the factors which should be included in the legislation on page 13 of this Statement. API believes their addition would avoid some of the vagueness which is reflected in the substitute 15/

3. Promulgation of the standards --

API also strongly supports the promulgation of the standards "by rule on the record after opportunity for a hearing in accordance with Sections 556 and 557 of Title 5, United States Code." API believes the use of this procedural safeguard will ensure that the very difficult and sophisticated scientific issues inherent in evaluating "risk studies" and preparing notice for affected persons, are adequately considered and sufficient information developed to make informed decisions.

API also endorses the provision calling for recommendations from a panel of scientific experts and from representatives of labor, business, and state and local agencies. API, as earlier stated, believes the process should entail the participation of a broad range of experts, especially those reflecting the viewpoints of potentially affected employers and employees.

15/ Both the factors for considering study and nonstudy individuals would benefit by the inclusion of provisions which are more specific. API believes this is preferable to leaving such issues to be resolved later on the basis of Report language.

4. Effect of Notification on Other Laws --

API supports the inclusion of provisions which would prohibit the use of any notice, finding or determination to a studied or nonstudied individual as a legal basis for damages or compensation award and prevent its introduction as "evidence" in a legal action or worker compensation proceeding. Notwithstanding the efforts made by the bill to make the review of "risk studies" more scientifically sound, the procedures will never provide the type of due process protections embodied in a civil trial or workman's compensation proceeding. Moreover, the likelihood that such evidence could cause prejudicial inferences to be drawn by a fact-finder, such as a jury, supports its inadmissibility in similar proceedings.

B. Shortcomings of the Quayle Substitute Legislation

API believes there are three significant shortcomings in the Quayle substitute. First, the bill would apply to studies which address other than occupationally related exposures to hazardous substances. This is a major expansion of the scope of the legislation, even beyond that contemplated in S. 79. It could involve the review of studies addressing vastly different kinds of exposures than those involved in the workplace. Even assuming that there is a need for such a program to deal with workplace exposures, there is a lack of evidence supporting the expansion of such a program into new areas, such as environmentally related exposures.

Generally, studies done on community populations have not been designed to test causal associations. Accordingly, they do not provide sufficient information upon which to base notification decisions.

In addition, many community population studies, such as those potentially called for under Section 110 of the Superfund Amendments and Reauthorization Act, will be readily available to the public because they are part of the administrative record associated with a Superfund site cleanup action. This open access policy is reinforced by the "community relations" requirements contained in the National Contigency Plan. EPA, under these requirements, must keep local citizens apprised of developments associated with studies and activities pertaining to the particular Superfund site.

API maintains that the many positive attributes of the Quayle substitute are undercut substantially by this significant expansion of the program. It could severely complicate and delay the issuance of standards because of their need to accommodate such a broad range of exposures. The bill should be limited to occupationally related studies and exposures.

A second area of concern pertains to the peer review procedures. Presumably, these peer groups will be reviewing specific studies and making recommendations as to whether and whom to notify. The peer review procedure is far too insulated and there should be additional safeguards to ensure adequate consideration of the evidence.

For example, there are no criteria for selecting the peer review groups. 16/ It is possible that there will be numerous peer review groups, perhaps one per agency. In addition to the burdensome aspects, the numerous groups heighten the likelihood for inconsistencies in the application of the standards.

In addition, the use of informal rulemaking procedures (5 U.S.C. § 553) to implement the peer review group's recommendations guarantees interested persons only a 30-day comment period and will not ensure that a public hearing will be held. This is less time and opportunity for input than that provided in S. 79. API believes Sections 556 and 557 of the APA, or requirements to their effect, should be included in reviewing the application of the standards by the peer review groups.

A third concern is that the costs of the process will be passed on, by some means, to private employers. API believes that as in earlier versions of the substitute, a provision should be included to prevent the costs of notification or other program provisions from being imposed on

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16/ API is concerned that only governmental employees or those reflecting limited view points may be part of the review process.

or assessed from parties other than the federal government, unless such costs are assumed on a wholly voluntary basis.

Senator **Quayle**. Thank you very much, Dr. Arp.

Finally, on behalf of the Chemical Manufacturers Association, George Rodenhausen, who is accompanied by Dr. Bruce Karrh.

Mr. Rodenhausen, please proceed.

Mr. **Rodenhausen**. Thank you, Mr. Chairman.

My name is George Rodenhausen. I am Director of Environmental Health and Safety Affairs for Celanese Corporation, recently merged with American Hoechst Corporation. I am appearing here today on behalf of Chemical Manufacturers Association, CMA, where I serve as Vice Chairman of the Health and Safety Committee.

Dr. Bruce Karrh, Vice President of Safety, Health and Environmental Affairs at the du Pont Company, is with me today to respond to questions.

The chemical industry has a longstanding commitment to worker health and safety, and as part of that commitment, CMA supports the goal of an appropriate, scientifically-based worker notification program. I am here today to express that support and also to share with you our specific concerns about S. 79.

On one point, we should all agree. Workers must be told of significant risks to their health arising from exposures on the job. In fact, the chemical industry has long had a policy of notifying workers of such risks.

But notification is not without costs. There is the dollar cost, of course; but there is a more important cost, the one to people. Unnecessary notification can result in anxiety to workers and their families, and therefore, accuracy of the notification is essential.

Any risk notification plan should take into account certain scientific principles. The first step is to determine if a true hazard exists, that is, whether exposure to a given substance or agent is likely to result in disease in humans.

The second step is to identify the level and duration of exposure which may significantly increase the risk of developing the disease.

And finally, all determinations of risk should consider all appropriate medical, health and epidemiological principles which are detailed in our written statement.

S. 79 does not have a sound scientific standard to determine who should be notified. The bill would improperly permit notification of personal risk based on a single animal or laboratory study.

The bill would also permit notification if a study shows that a substance may cause adverse health effects, even if the chance of those effects occurring is small.

And the bill would permit notification if either the intensity or the duration of exposure is comparable to those in the study. This is simply bad science. The only way to determine risk is to consider both the level of exposure and how long a person is exposed.

We are especially concerned with specifying a minimum number of notifications every year. This provision throws science out the window. The quota, rather than proper notification, becomes the goal. An arbitrary quota has no place in a system that bases its determination on sound scientific principles, and we urge that it be dropped.

With regard to the Risk Assessment Board, I would like to mention two suggestions.

First, the composition of the Board would be improved by opening membership to qualified experts, regardless of institutional affiliation. And second, the Board should be able to appoint expert panels—very much like your Peer Review Panels—to study specific substances to assure that the best scientific judgment is brought to bear on each one.

Finally, the bill is likely to have a significant impact on tort litigation and workers' compensation. The purpose of the notification is to protect and preserve health by informing workers of increased risk. The notification program will not determine that a worker has been injured. Therefore the bill should assure that the notification and findings will not be used in legal or administrative proceedings.

Senator Quayle, the legislation you have recently introduced, S. 638, would address many of our concerns. Your bill offers constructive approaches worthy of the Subcommittee's consideration. And in particular, the findings of S. 638 more accurately reflect the extent of occupational disease in this country.

In conclusion, CMA supports an appropriate, scientifically-based worker notification plan, and to help advance that goal, we stand ready to work with the Subcommittee in addressing the concerns raised in our testimony.

Thank you. Dr. Karrh and I will be happy to answer any questions you may have.

[The prepared statement of The Chemical Manufacturers Association represented by Mr. Rodenhausen follows:]

STATEMENT OF THE CHEMICAL MANUFACTURERS ASSOCIATION ON S.79, THE HIGH RISK OCCUPATIONAL DISEASE NOTIFICATION AND PREVENTION ACT OF 1987

Submitted to the Subcommittee on Labor
of the Senate Committee on Labor and
Human Resources

March 9, 1987

INTRODUCTION AND SUMMARY

The Chemical Manufacturers Association ("CMA") welcomes the opportunity to submit this statement on S.79, the High Risk Occupational Disease Notification and Prevention Act of 1987. CMA is a non-profit trade association whose member companies represent more than 90 percent of the productive capacity of basic industrial chemicals in the United States.

CMA and its member companies share the Subcommittee's commitment to reducing the incidence of occupational disease and to providing workers with safe and healthful workplaces. Indeed, the chemical industry has an outstanding record in workplace health and safety. Our member companies have pioneered the establishment of comprehensive programs to communicate hazard information to their workers and to protect workers from harmful effects of chemicals in the workplace. Many of CMA's member companies also have major on-going programs in toxicology, epidemiology, and medical surveillance. In addition, CMA and its members have supported effective regulation by OSHA, most notably the landmark hazard communication standard.

S.79 would create a new risk notification system beyond existing regulatory requirements. The core provisions of the bill would establish a new mechanism under which a Risk Assessment Board, formed entirely of government employees, would identify populations of workers exposed to occupational health hazards, and notify each individual worker within certain of those populations. The key trigger for identification and notification could be a single scientific study, perhaps an animal or laboratory study. The bill also contains provisions for occupational and environmental health centers, research, training, and education.

We fully share and endorse the goal of identifying and notifying employees at significant risk of occupational diseases. We believe that, in crafting any risk notification plan, the Subcommittee should take into account certain principles and concepts:

1. The OSHA hazard communication standard, as a comprehensive approach to informing workers of hazards in the workplace, should be built upon and expanded to cover all employees.

2. The determination of worker populations actually at risk, for purposes of notification, should rest upon sound scientific principles, and should be based upon the recommendations of an expert peer review panel for each substance in question.

3. Determinations of risk should consider all applicable medical, health, and epidemiological principles, including consistency of association; specificity of association; strength of association; dose-response relationships; biological plausibility; temporal relationships; statistical significance; significance of conflicting and negative studies; the role of contributing causal factors; and the extent and seriousness of risk.

4. A decision to notify should be a two-step process. First, there must be strong scientific evidence that human exposure to a substance is likely to result in disease. Second, notification should be applicable only to employees determined to be at significantly increased risk in light of both the intensity and the duration of their exposure.

5. Based upon these scientifically sound determinations, employers should have the option to notify employees who are subject to a real and

significant risk of adverse health effects from workplace exposures, with the government authorized to provide notification if the employer chooses not to do so.

6. Notified workers should be informed of the nature and magnitude of possible health effects associated with their exposures, the role of contributing risk factors (such as smoking, diet, and alcohol consumption, as applicable), and appropriate types of beneficial medical surveillance.

7. Any notification bill should expressly provide that neither the findings that support a notification nor the notification itself may have any effect on a claim for compensation or damages, nor be admissible as evidence in any litigation or workers' compensation proceeding.

8. The standards for judicial review should specify that a determination to notify may be set aside if unsupported by substantial evidence on the record.

S.79 is an improvement over the legislation proposed in the last session of Congress. Nevertheless, it remains flawed in significant respects. As we discuss in greater detail below, S.79

- -- rests on an inaccurate perception of the scope of the occupational disease problem;
- -- contains a trigger mechanism that may misidentify persons at risk of occupational disease, and hence result in the notification of many workers who are not in fact at risk;
- -- contains a statutory quota that has no scientific basis, and hence threatens to politicize the identification of worker populations to be notified;
- -- fails to provide the Risk Assessment Board with the best available expertise;
- -- does not offer adequate procedural controls to ensure that the Risk Assessment Board's determinations are based on all relevant scientific evidence, and does not provide for adequate judicial review of those determinations; and
- -- fails fully to account for existing statutory and regulatory provisions, such as those in OSHA's hazard communication standard, which provide a means of furnishing significant information about workplace hazards and risks to employees.

Senator Quayle has recently introduced legislation that would address many of these problems, both by improving the scientific basis for identifying worker populations at risk and by evaluating the appropriateness of notification under a variety of circumstances.[1/] We believe that many concepts in Senator Quayle's approach are worth the Subcommittee's attention as it considers S.79. We shall return to that proposal below, in the Conclusion to this statement.

I. THE FINDINGS IN THE BILL DO NOT ACCURATELY REFLECT CURRENT SCIENTIFIC VIEWS CONCERNING OCCUPATIONAL DISEASE.

It is important to keep the problem of occupational disease in perspective. Some of the findings in Section 2 of S.79 appear to reflect a notion that gained currency among some interest groups several years ago -- that there is an "epidemic" of occupational disease in the United States, and that a significant portion of cancer cases are occupationally-related. Almost all experts now agree that the earlier estimates were mistaken, and were based on faulty methodology. The landmark study by Professors Doll and Peto, commissioned by the United States Office of Technology Assessment, demonstrated that earlier estimates were much too high, and concluded that only approximately 4% of cancer cases in the United States are work-related.[2/] While

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[1/] S.638, 133 Cong. Rec. S2703 (March 3, 1987).

[2/] Doll & Peto, The Causes of Cancer: Quantitative Estimates of Avoidable Risks of Cancer in the United States Today, 66 J. Nat'l Cancer Inst. 1191, 1245 (June 1981).

occupational causes of cancer and other diseases must certainly be reckoned with, they pale in comparison to such other factors as smoking, diet, and alcohol as contributors to the nation's health problems.

Accordingly, while CMA supports the goal of notifying workers who are at significant risk due to exposures in the workplace, we also believe that it is important to recognize the limited nature of the problem. The findings section of the bill in particular exaggerates the threat that workplace hazards present to the health of the American public.

II. THE BILL WILL MISIDENTIFY EMPLOYEES AT RISK, AND HENCE WILL RESULT IN UNNECESSARY AND UNHELPFUL EMPLOYEE NOTIFICATIONS.

A number of bills introduced in the last Congress would have required notification of a population of employees on the basis of a specified percentage overincidence of a disease associated with workplace hazards.[3/] CMA and others argued that percentage trigger criteria by their nature are arbitrary and unscientific, and we applaud the abandonment of such criteria in S.79. As it presently stands, however, the bill will lead to the notification of substantial numbers of employees who are not in fact at risk. An overestimation of occupational health hazards of this magnitude may in turn produce a serious misallocation of resources.

[3/] E.g., S.2050, 99th Cong., 2d Sess. (1986).

A. To Rest Notification on Merely One Study of Any Kind Will Result in the Notification of Many Workers Not Actually at Risk.

S.79 defines "occupational health hazard" as

> a chemical, a physical, or a biological agent, or an industrial or chemical process, found in the workplace for which there is statistically significant evidence (based on at least one study conducted in accordance with established scientific principles) that acute or chronic health effects may occur in exposed employees.

The bill goes on to require the notification of certain employees who are "exposed to an occupational health hazard at intensities or for durations comparable to [those in the study]."

CMA endorses the requirements that evidence triggering notification be statistically significant, and that any studies relied upon be conducted in accordance with established scientific principles. These two provisions go a long way toward correcting some of the shortcomings in earlier bills. Substantial problems remain, however, with this new trigger for notification.

It appears from the face of the bill that any study could potentially serve to trigger full notification, even a single animal study or in vitro experiment. If an animal study, for example, shows that the agent or process in question may produce health effects in exposed employees, then the Risk Assessment Board is free to notify any and all employees whose exposures equal those used in the study, either in intensity or in duration. These provisions overlook some fundamental scientific principles.

First, extrapolation from animal or in vitro studies to live human populations is a notoriously risky business. It is not good science to rely on a single animal experiment for making precise estimates of disease risk.[4/]

Second, the provision that a study need show only that an agent may cause health effects largely vitiates the requirements that the study be conducted in accordance with established scientific principles and that the results be statistically significant. It is entirely possible, for example, that a properly conducted study might show, at a suitable level of significance, that a particular agent has only a remote possibility of contributing to a particular disease. Another study might show that some other agent unmistakably causes that same disease. Under the present language of the bill, these two findings would have much the same effect, yet their consequences for notification should properly be quite different.

[4/] See e.g., Gulf South Insulation v. United States Consumer Product Safety Comm'n, 701 F.2d 1137, 1146 (5th Cir. 1983). Witness also the controversy over whether the results of animal studies on the safety of sugar substitutes can properly be extended to the consuming public.

Third, the bill opens the possibility of notification whenever employees are exposed to an agent "at intensities or for durations comparable to [those in the study]." This use of the word "or" is simply bad science. As a rule, the effects of intensity and duration are interactive: A very low intensity of exposure is safe for longer periods than is a higher intensity. Yet the language of the bill ignores this elementary principle. Suppose, for example, that a study shows a high intensity of exposure to a certain agent to be unsafe for long durations. The bill could nonetheless be read to require notification even to employees exposed to the high level for very brief periods, or exposed to the long duration at extremely low levels of intensity -- conditions under which the study may have found no harm whatsoever.

These problems arise, in part, from S.79 having borrowed its definition of "occupational health hazard" from the language of OSHA's hazard communication standard. 29 C.F.R. § 1910.1200(c). The analogy is flawed, however. The definition in the hazard communication standard triggers a requirement that workers be notified that a chemical in the workplace can be hazardous if not handled properly. But the hazard communication standard does not require any determinations of particular levels of risk to employees -- or, indeed, of any specific risk whatever. Accordingly, the definition used in that standard is invalid when used as a basis for notifying workers that they are individually at a significant risk. While S.79 qualifies the effect of the definition, by requiring that employee exposures be at intensities or for durations comparable to those in the triggering study, the qualification nevertheless fails to render the definition suitable for the purposes of S.79, for the reasons explained above.

In short, while notification on a showing of clear risk is certainly appropriate, S.79 would provide for the notification of employees even in the absence of reliable evidence that those employees are at any risk of an occupational disease. We recognize that the Risk Assessment Board is authorized to consider additional factors as well, including "estimates of increased risk of death or disease in exposed human populations relating to . . . duration and intensities of exposure." The role of such factors in the Board's decision-making process, however, is not spelled out. Moreover, while the Board must take as its "first priority" the designations of populations "likely to benefit from medical surveillance or health counseling," the bill otherwise fails to take into account "the potential effects of failing to provide notice . . . and of providing incorrect notice"[5] -- in short, whether notification "would be medically beneficial and ethically appropriate."[6] Just as there are disadvantages to omitting notification when it should be given, there are also pronounced disadvantages to giving notification when it is uncalled for. We return to this issue below, in Part III.D.

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[5] S.638, 133 Cong. Rec. S2703, S2703 (March 3, 1987).

[6] 133 Cong. Rec. S1982, S1983 (Feb. 5, 1987) (proposal of Sen. Quayle).

B. A Specified Quota of Notifications Each Year Would Seriously Undermine the Scientific Basis of the Bill.

S.79 would require the Board to "notify or coordinate notification of not less than 100,000 employees per year," and also would enjoin the Board to make "every reasonable effort to notify or coordinate notification of not less than 300,000 employees per year." These provisions represent a pronounced departure from scientific principles and reasoning, and can only frustrate the goal of scientific validity that underlies the bill. If the number of scientifically justifiable notifications in a given year failed to reach 100,000 -- or possibly 300,000 -- the Board would have little choice but to make at least some of its decisions on the basis of other than scientific factors. The consequence would likely be notifications on an ad hoc political basis, rather than on sound scientific evidence. Such a quota can have no useful place in this legislation, and we urge that it be dropped.

C. The Bill Fails to Assure Adequate Expertise on the Board and Fails to Provide Procedural Controls on the Decision-Making Process.

Risk Assessment Board. The bill requires that all members of the Risk Assessment Board be drawn from career or commissioned Public Health Service employees. Without intending to question either the competence or the dedication of those in the Public Health Service, we nevertheless believe that this limitation on the composition of the Board is unduly restrictive: It is essential that the Board have available to it the best possible expertise, from whatever source. Accordingly, the most qualified experts should be eligible for appointment to the Board, whether they come from industry, labor, or the academic community. We suggest that the bill require the Secretary to seek recommendations on Board membership from an independent body that is both well-informed and disinterested. Even so, however, no five-member panel can possibly have ready access to all of the complex, technical information that the Board's deliberations will require. We therefore further suggest that additional ways be found for the Board to tap outside expertise on a regular basis. For example, the board should be able to appoint expert panels to study specific substances to assure that the best scientific judgment is brought to bear on each one.

Hearings. The facts to be established by the Risk Assessment Board are highly specific in nature. As a rule, the

Board's findings will follow from the results of scientific studies, interpreted in the light of expert opinion; and the findings will, in some cases, affect the lives of very large numbers of workers. But those findings may not always be free from doubt. Accordingly, in order to bring to the Board's proceedings the greatest possible degree of reliability, we suggest that those proceedings include hearings at which interested parties may present their own witnesses and cross-examine one another's witnesses. Such testimony will help to ensure that the Board's decisions are based on the best scientific information available.

Reevaluations. Even the most soundly based scientific determinations can never escape all possibility of error; and it may happen, from time to time, that new scientific evidence will absolve a substance previously thought to constitute a health hazard in the workplace. To provide for such possibilities, we suggest that the bill empower the Risk Assessment Board to rescind a notification, when appropriate, by informing individuals previously notifified that they are not in fact at risk. Such a provision would help to relieve unwarranted anxiety among employees and their families and should help to reduce the cost of health surveillance and monitoring that proves to be unnecessary.

Judicial Review. The grounds upon which a reviewing court may set aside a determination by the Risk Assessment Board, as specified in the bill, are drawn from among those in the Administrative Procedure Act ("APA"). 5 U.S.C. § 706(2). The bill includes most of the APA grounds that are generally applicable to administrative notice-and-comment rulemaking. Missing from the bill, however, are any grounds that would enable the reviewing court to pass directly on fact-finding by the Board, particularly a provision that the reviewing court may set aside agency action "found to be . . . unsupported by substantial evidence . . . ." 5 U.S.C. § 706(2)(E). In view of the Board's fact-finding mission, the failure to provide any provision under which a reviewing court might consider the factual basis for the Board's conclusions would render judicial review an empty exercise. Accordingly, we urge that the section on judicial review include a "substantial evidence" test.

D. Indiscriminate and Overly Extensive Notification Can Also Be as Detrimental as Insufficient Notification.

Both in its imposition of a quota and in the notification criteria discussed above, the bill seems to have been drafted on the assumption that, if some notification is good, then more must be better. We must respectfully disagree.

Unnecessary notification carries its own harmful effects. When a worker is notified of risks that do not exist, the consequences are likely to include unnecessary distress and anxiety to the employee and his or her family, as well as effects on future insurability and employment. While S.79 properly prohibits discrimination and reduction of benefits on the basis of an employee's inclusion in a group deemed to be at risk, the burden of identifying and proving such discrimination must ultimately fall on the employee. In any event, a bar against discrimination is no substitute for properly identifying groups at risk in the first instance. Medical screening and follow-up in themselves can also carry definite hazards -- e.g., the risks involved in x-rays and other tests that may not be fully dispositive in every case -- and so should not be undertaken capriciously. In short, workers ought not to be subjected to the psychological, social, and medical consequences of notification unless the basis for notification is considerably more trustworthy than is provided for in the present bill. Scarce medical resources likewise should not be allocated on an unreliable basis.

Beyond the costs to individual employees and their families, overly extensive notification would likely carry a social cost as well: a substantial increase in the numbers of unwarranted claims in workers' compensation and tort litigation. S.79 was evidently framed with this possibility in mind, for Section 10(g) seems to be intended to guard against such an explosion in litigation. But that provision is not drafted tightly enough to do the job. S.79 should specify that neither a notification nor the findings that prompted it may constitute a legal basis for damages or for any compensation award, nor shall be admissible as evidence in any legal action with respect to any matter or in any proceeding relating to workers' compensation.[7/]

In addition, so long as the trigger criteria in S.79 -- and the statutory quota -- empower or require the Risk Assessment Board to notify workers who are not actually at risk, frivolous claims and unjustified awards are all but inevitable. Such claims and awards will constitute an unnecessary and unproductive burden on state administrative bodies, workers' compensation funds, tort defendants, and the courts -- and hence, on society as a whole.

E. Contents of Notification Should Include Contributing Risk Factors and Appropriate Medical Surveillance.

Notification is most useful when it can result in a worker taking affirmative steps to protect his or her health. In many cases, the contents of the notification itself can offer potentially life-saving advice. Following exposure to asbestos, for example, a worker who smokes can improve his or her chances for survival just by abstaining from tobacco. We suggest that the bill be amended to require that notifications include information on contributing risk factors that may bear upon the degree of risk, where there is medical evidence to support such information.

[7/] See S.638, 133 Cong. Rec. S2703, S2704 (March 3, 1987).

It is also important to recognize the limitations of medical testing and surveillance in the context of occupational disease. Testing and surveillance can be effective in helping to prevent or treat some specific diseases; but in the case of many others, intervention cannot provide workers with any meaningful protection.[8/] The Board should be required to determine the appropriate type of beneficial medical surveillance.[9/] In making this determination, the Board should consider the limitations inherent in testing and surveillance. CMA supports research designed to improve health surveillance techniques.

III. EXISTING AUTHORITIES AND REGULATIONS ALREADY ASSURE A SUBSTANTIAL FLOW OF INFORMATION TO WORKERS REGARDING OCCUPATIONAL DISEASE HAZARDS.

There can be no question that workplace exposure to certain chemicals and other hazardous substances at unsafe levels, particularly over long periods of time, can lead to the development of serious illness. In taking up these problems, however, the Subcommittee should recognize existing laws and regulations. Since the enactment of the Occupational Safety and Health Act, both OSHA and industry have made major gains in

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[8/] In the case of mesothelioma, for example, treatment is ineffective regardless of when the disease is first detected. The treatment for, and outcome in, leukemia are the same regardless of when the disease is first detected. In the case of lung cancer, the improvement in survival from early detection is so low that the American Cancer Society has rescinded its previous recommendation for periodic chest x-rays.

[9/] *See* S.638, 133 Cong. Rec. S2703, S2704 (March 3, 1987).

addressing the issue, both by lowering exposure levels and by providing information to workers about risks and protective measures. We urge the Sucommittee not to duplicate existing regulation, but rather to build upon the OSHA activity and employer responsibilities that are already in place.

For example, OSHA has recently promulgated a generic hazard communication standard which imposes extensive obligations on all chemical manufacturers and importers, and on all employers in the manufacturing sector, to communicate information on workplace hazards to employees, including information on the risk of occupationally-related diseases. The hazard communication standard specifically requires chemical manufacturers and importers to identify hazardous substances that they produce or distribute, on the basis of the best available scientific data, and to develop material safety data sheets (MSDSs) that include comprehensive information on the nature of hazards presented and appropriate protective measures against those hazards. Among their other obligations, employers must implement training and education programs to inform their workers about the hazards to which they may be exposed.

One instance of the bill's duplication of existing authority arises in the definition of "occupational health hazard." That provision currently includes substances that result in acute health effects, such as agents that damage the skin or eyes. Such acute effects, however, are expressly covered by the hazard communication standard. There is no need for a separate statutory structure to address the same risks. OSHA has initiated rulemaking proceedings with a view toward expansion of the hazard communication standard to cover employers outside the manufacturing sector. CMA supports extension of the standard to all employees.

The hazard communication standard is supplemented by OSHA's employee exposure and medical records access rule, which requires all employers to make available to any employee or designated representative all exposure and medical records. Employers must retain such records for at least 30 years.

OSHA and NIOSH possess significant authority under the Occupational Safety and Health Act, and major steps have already been taken in implementing those statutory authorities to assure notification of workers at risk of occupational diseases. Section 20(a)(6) of the OSH Act, 29 U.S.C. § 669(a)(6), gives NIOSH the specific responsibility to investigate whether particular workplaces present hazardous conditions, and to inform affected employees of its determinations. NIOSH has extensive research and investigation authority under Section 20, including the authority to require monitoring of exposures and to conduct medical examinations and tests. 29 U.S.C. § 669(a)(5); 42 C.F.R. § 85.5(a). NIOSH must distribute the results of any such monitoring and testing to employees. 29 U.S.C. § 669(d).

OSHA has also promulgated or proposed specific standards for substances such as cotton dust, acrylonitrile, asbestos, lead, ethylene oxide, benzene, and formaldehyde. These standards have specific labeling provisions related to occupational disease risks, and include provisions for surveillance, monitoring, and testing. OSHA and NIOSH have access to MSDSs, lists of hazardous chemicals, and exposure and medical records, and can use this information to develop additional health standards, including surveillance and testing requirements.

Finally, through the National Toxicology Program and other programs, the Federal Government itself is involved in conducting, sponsoring, and evaluating research, including toxicological and epidemiological studies, on the effects of chemicals used in the workplace. The appropriate government agencies have ample means by which to convey the results of that research to affected worker populations, as the need arises

Existing authorities are far-reaching. The hazard communication standard in particular will result in the flow of extensive additional information to workers; and its requirement that employers institute and maintain a comprehensive hazard communication program will lead even more employers to adopt effective overall occupational health programs for their employees, including medical surveillance and testing. These authorities should not be ignored, as they offer a sound base upon which to implement the goals of notifying workers at risk of occupational disease.

CONCLUSION

CMA agrees that we must continue to find ways to strengthen existing systems for informing workers of significant health risks in the workplace. In its present form, however, S.79 does not provide a sound basis for doing so. Its central mechanism -- the any-one-study criterion for determination of an occupational health hazard -- is scientifically unsound, and so will lead to misidentification of workers at risk. And the bill does not fully account for existing regulatory authorities, particularly OSHA's hazard communication standard, which already covers acute health hazards.

As noted above, we believe that Senator Quayle's recently introduced legislation, S.638, contains a number of provisions that the Subcommittee should consider in the course of its deliberations on S.79:

-- a scientific basis for identifying populations to be notified that does not depend on any arbitrarily chosen finding or event, and which includes specific provisions for peer review;

- findings that realistically take into account the "substantial progress . . . made in controlling the exposure of individuals to [hazardous] substances and agents";
- a provision that would go a long way toward properly insulating tort suits and workers' compensation proceedings from the notification process; and
- a balancing test that expressly considers the suitability of notification in light of a broad range of relevant factors.

In short, CMA and its member companies support efforts to arrive at an appropriate, scientifically-based worker notification plan. To help advance that goal, we stand ready to assist the Subcommittee in addressing the concerns raised in this testimony.

Senator **Quayle**. Let me address a couple questions to the panel. The first is the same question I asked the last panel. What is the biggest problem with the proposed legislation, S.79? Is it the notification aspect, or is it the liability aspect? Which one gives you the most heartburn?

Mr. Knebel?

Mr. **Knebel**. Well, Senator, we see the cost as a result of the litigation to be staggering; but even before you get there, you have got some very serious flaws in the whole procedure. And I think the other point that you cannot ignore is the notion of trying to quantify the notification system. It takes it out of the realm of a professional approach and puts it into a scorekeeper's ballpark.

On balance, we think both aspects are seriously deficient.

Senator **Quayle**. Well, let us assume that you could work out the liability aspect and the notification aspect. I guess the only way you could work out the liability is to make sure that that there were not additional liabilities to the employer. I presume that would be your response.

On the notification, I guess you would have to come down and answer this question first—whether there is any duty to notify employees where there is a certainty from scientific data that the employees are at risk of contracting a disease.

Mr. **Knebel**. When you put that word in there, "certainty", Senator, we would go along with you. But until then you have got a real crapshoot on your hands. And I think, frankly, if you turn this panel loose, or the proposed panel loose, the way it is, without any safeguards, there is absolutely no way that you could control it, and on the litigation side, there is absolutely no way you can keep the notification out as evidence.

Senator **Quayle**. Do you think you could control the panel, if in fact it was a group of scientists who understood the data that was in the report, that had certain guidelines on how notification ought to be given, whether it ought to be individual or through the news media, through the unions, or whatever type of notification?

Do you think we could put a proper amount of controls on the notification process that would make it acceptable?

Mr. **Knebel**. Well, all of these things would help, but we would like to see the final product.

Senator **Quayle**. Dr. Arp, what about it? Is notification the biggest problem to work out, or is it the liability?

Dr. **Arp**. Senator, my biggest problem with the proposal is its failure to really address preventive measures. We believe prevention should be the key, and this new bureaucracy would represent an additional drain on an already scarce resource devoted to prevention of occupational illness.

Senator **Quayle**. Before you get to the prevention, the additional liabilities through medical monitoring and things of that sort that are encompassed in the bill, does that pose significant problems, or do you think that is something that could be worked out?

Dr. **Arp**. I have not analyzed the liabilities. Perhaps Dr. Raabe could speak to that.

Dr. **Raabe**. Senator, our belief is that in the absence of very rigorous scientific determination by the Board, which is absent from both bills right now, although you are leaning toward it much better, there is no way to control what the outcome is going to be, and therefore you will always hear the litigation, the liability, the costs as driving the concern.

We just do not feel comfortable that there is an adequate rigor in the scientific process. That is why we would advocate that the NIOSH decision-type logic be explicitly included in the legislation.

Senator **Quayle**. Yes, that is the direction that we went, and we tried to include that in our legislation. And we are trying to establish the limitations and not impose any additional liabilities, whether it be tort or workmen's compensation or whatever. And I guess what I am just trying to figure out is really, which one is of the biggest concern to industry.

I guess if you are saying—and I am not sure I hear you right—if we work out the notification process correctly, that the liability will not be that much of a problem?

Dr. **Raabe**. The liability will always be a problem. And to the extent that you can build strong walls to contain it, we certainly look favorably toward that. But the absolute bottom line is if the worker notification is to float, then to do it effectively, the best science is what is going to make the bill acceptable or unacceptable, because the liability is going to be there.

Senator **Quayle**. It is going to be there no matter whether we try to limit it or not?

Dr. **Raabe**. That is my belief.

Senator **Quayle**. That would be your position on that. All right. Mr. Rodenhausen?

Mr. **Rodenhausen**. On behalf of the CMA, I think you have asked us to choose between the top two of the fifteen top concerns we have with S. 79, and it is very difficult to do. I think they are related, in that the liability concern is to a large extent because of the bad science which is in the bill and the fact that there will be gross over-notification leading to, probably, a large number of unjustified lawsuits.

Following that logic, it would seem reasonable that if the good science could be put back in the bill at the front end of the process, the liability concerns would diminish. But given the state of society and the likelihood of lawsuits being brought regardless of what the rationale, that liability provision is very important to the industry.

Senator **Quayle**. Let me ask one other question. In my view, risk notification and hazard communication are quite different. It looks like the definition of occupational health hazard which is in S. 79 is appropriate for a hazard, but not appropriate for a risk. And it seems that we have got the two somewhat mixed up; that there seems to be the same definition of a "hazard" as for a "risk" and that is just not the case. If something is poisonous, you can identify that as a "hazard", but if it is handled properly, there is not going to be a "risk". There is certain risk, but if it is handled properly, there will not be any risk.

Yet on the other hand, we may be complying with health and safety standards, but there may be some evidence that shows that there is still risk to one's health.

Do you find this somewhat confusion that has been picked up in S. 79, the general comments, Mr. Rodenhausen?

Mr. RODENHAUSEN. Yes. I think what you have pointed up is a good example of how S. 79 fails to acknowledge the current laws that are in effect. Basically, hazard communication is already taken care of by regulations in effect, and what this bill does is borrow the same language from that hazard communication standard which means it would address the same universe of chemicals, which would be duplicative.

There is a second example in that it also addresses acute hazards as opposed to chronic long-term diseases, which I think is really the purpose of the bill.

There are other examples of how, by failing to acknowledge the existing laws in effect, the bill essentially duplicates some functions carried out already.

Senator QUAYLE. Dr. Arp, have you got any comment on that definition of risk notification and hazard communication?

Dr. ARP. Yes, sir, and again, going back to the fundamental of prevention, the fundamental tenet is, as you have pointed out, control of exposure. In the absence of the exposure and in the absence or, more preferably, with a controlled exposure, the hazard simply does not manifest itself into a risk.

Again, we would advocate preventive measures.

Senator QUAYLE. Do you think that there is a confusion in this bill in the definition of "hazard" versus the definition of "risk"?

Dr. RAABE. Yes, absolutely, Senator Quayle. Following up on what Mr. Rodenhausen said, and your own definition is quite accurate. "Hazard" is the intrinsic ability of a material or substance to do harm. "Risk" is the probability of that harm taking place. And what you hear us saying is, collectively, one, there are procedures and systems in place that address the vast majority of the hazard identification and hazard communication. OSHA even addresses the risk.

There is some question of who this bill is actually intended for as they are currently laid out, because there are very few individuals that are falling between the cracks right now. So it is sensed as duplicative in a lot of ways.

But clearly, it should be defined at the level of risk, not at the level of hazard, because then you are really muddying the waters.

Senator QUAYLE. Mr. Roy?

Mr. ROY. Senator, you have defined the difference between "hazard" and "risk" perfectly, so I cannot add any more to that.

Senator QUAYLE. But you do feel that there is a confusion in the bill?

Mr. ROY. There is a big confusion between the two.

Senator QUAYLE. Okay. Gentlemen, thank you very much.

Our final panel is Allyn Tatum and Craig Berrington.

Our first witness is Allyn Tatum, on behalf of the International Association of Industrial Accident Boards and Commissions.

Mr. Tatum?

STATEMENTS OF ALLYN TATUM, ARKANSAS COMMISSIONER FOR WORKERS' COMPENSATION, ON BEHALF OF THE INTERNATIONAL ASSOCIATION OF INDUSTRIAL ACCIDENT BOARDS AND COMMISSIONS; AND CRAIG BERRINGTON, GENERAL COUNSEL, AMERICAN INSURANCE ASSOCIATION, ACCOMPANIED BY TOM O'DAY, ASSOCIATE VICE PRESIDENT, ALLIANCE OF AMERICAN INSURERS, AND WILLIAM C. ALDRICH, VICE PRESIDENT FOR GOVERNMENT RELATIONS, HARTFORD INSURANCE GROUP

Mr. TATUM. Thank you, Senator Quayle.

I am here as a last-minute substitute for Robin Waller, from the State of Connecticut, who is Chairman of the Legislative Committee for the Industrial Accident Boards and Commissions. I am going to call that the "IAIABC" from now on, because it is a long and unwieldy title. It is an important organization in that it is made up of the State Industrial Accident Boards and Commissions throughout the United States, as well as the Boards and Commissions in the Canadian provinces.

In addition to that, we have literally thousands of associate members that touch every aspect and field involving workers' compensation.

I would like to thank you for allowing us an opportunity to have input today on this important issue. State workers' compensation agencies are well aware that occupational disease is a very important problem. Our many decades of experience in dealing with occupational disease, Senator, teaches us that it is also an extremely complex issue.

However, the States are dealing with the problem, and we are compensating workers with occupational diseases arising out of and in the course of their employment.

To the extent that any legislation deals with medical research, education, treatment, or prevention of occupational disease, our organization will support it. However, we have historically opposed any legislation which intrudes into the province of the States in determining workers' compensation issues. We will continue to oppose such legislation.

While the IAIABC has not met this year, I would like to read into the record a resolution which we passed last year, last fall, at our convention in Louisville, Kentucky, because I think it is relevant.

> Whereas the 70th Annual Convention of the IAIABC affirmed the primary role of State workers' compensation agencies in the administration of occupational disease claims and encouraged the Federal government to concentrate its efforts on scientific and medical research.
>
> Whereas proposals exist in Congress which are predicated on the assumption that State workers' compensation laws are inadequate to respond to occupational disease claims; and
>
> Whereas other proposals in Congress advocate the creation of an extensive and expensive Federal monitoring bureaucracy providing injunctive and punitive power over employers and others involved in the State administration of workers' compensation.
>
> Now, therefore, be it resolved that the IAIABC reaffirms the principle that State workers' compensation agencies are the primary administrators of occupational disease claims; and commends Federal efforts in the area of scientific and medical research and opposes legislation which would supplant State workers' compensation agencies in the field of occupational disease or create a monitoring bureaucracy, armed with the power to interfere with State compensation administration; and fi-

nally, we recognize the need and obligation to respond to the plight of disease victims and encourage all our member States to continue their efforts to adequately address the needs of occupational disease victims.

Senator, apparently, many feel that the States do not do their job in the occupational disease area. Well, we do not do medical research, and we do not provide preventive treatment, and we do not do largescale notification about occupational disease. But we can and we do provide an avenue for deciding the legal issues surrounding occupational disease and a forum to allow compensation for work-related occupational disease claims.

With regard to notification, Senator, if it is not undertaken with the utmost care, and unless adequate safeguards are provided, we fear that it will result in undue and, to a large extent, unnecessary glut of additional litigation in our workers' compensation systems.

With this increase in litigation comes an increase in cost of workers' compensation.

To summarize, while the IAIABC has not yet taken a position on any current occupational disease legislation, I am reasonably certain that we would oppose S. 79 in its current form.

If another system is necessary outside the already existing Federal notification systems, the approach suggested, Senator Quayle, by your S. 638 would seem to provide more safeguards for preventing intrusion into the existing workers' compensation systems.

The IAIABC Legislative Committee plans to meet soon to further study your alternative.

Thank you very much, Senator.

Senator QUAYLE. Thank you very much, Mr. Tatum.

Our final witness today is Craig Berrington, General Counsel for the American Insurance Association, accompanied by Tom O'Day and Bill Aldrich.

Mr. Berrington?

Mr. BERRINGTON. Thank you, Senator.

We appreciate the opportunity to be here today to discuss S. 79. I am testifying on behalf of the American Insurance Association and also on behalf of the Alliance of American Insurers and the National Association of Independent Insurers. Together, the members of these three organizations write approximately 85 percent of all workers' compensation sold in the United States.

Workers' compensation is the product of one of the great reform movements of the 20th century, and we in the insurance business are proud to have been an important part of that reform and to have historically supported responsible measures to protect worker health. Indeed, we were strong early proponents of enactment of the Occupational Safety and Health Act.

But we are also in the position, Senator, of seeing how legislation actually operates. It is with that dual perspective on these issues that we in the insurance industry have examined S. 79. Good intentions are important, and we concur in the good intentions of S. 79; but good intentions are not enough. Legislation needs to be carefully drafted. We must not fall prey to the notion that a problem is so important that shortcuts should be utilized, procedural safeguards ignored, scientific standards trimmed, and the impact on the judicial system left unexamined.

In that regard, I would like to focus on three major areas of concern that we have—they will not come as any great surprise to you. The first area has to do with the lack of good science, in S. 79. We want to raise at least five specific problems there.

First, the two key definitions, "occupational health hazard" and "population at risk of disease", are not sufficiently clear. Moreover they are not, as I think has been made abundantly clear this morning, drawn tightly enough to make certain that a massive notification process is limited to those really significant and dangerous matters.

Second, we find, as have others, the notion of letting the Risk Assessment Board proceed on the basis of one study wholly insupportable.

Third, we are concerned that no directions are given to the Board to distinguish between epidemiological and clinical studies on the one hand and animal and laboratory studies on the other.

Fourth, we are concerned about the lack of professional scientific review of Board determinations. This needs to be corrected. I think the peer review process that has been set up in S. 638 is quite a good step toward that direction. We find it useful and necessary.

And finally, in the scientific area, we are concerned about the rigidity of the notice requirements set out in S. 79. The bill does not appear to allow for the tailoring of notice procedures to individual situations.

The second area is one that has also been of much concern. That is the area of liability potential. It is an extraordinary potential. We do recognize that S. 79 contains some language designed, apparently, to limit liability, but we are not yet convinced that it is possible with any language to wall off the liability potential of the bill.

We have three concerns. One is that notifications will place intense pressure on the workers' compensation system to presume the work-relatedness of individual cases, even though we know as a statistical certainty that that will not be the case.

Second, we are concerned that the actual notices will find their way into the workers' compensation system and civil proceedings, and if that happens, there is going to be a whole new class of litigation, including intentional tort lawsuits, which will obviate the workers' compensation system.

We are concerned, third, that notifications themselves will result in stress claims—not stress coming from the workplace, but stress coming from the notification. Indeed, it would be unusual for a person to get notification and not feel great stress. It would be extraordinary, combined with the notion earlier stated this morning that there will be possibly a large number of false positives, to combine those "false positives" with the influx into the workers' compensation system of stress claims based on the notification process. What an irony it would be for this notification legislation to become litigation legislation.

The third area I want to discuss quickly has to do with the procedural aspects of the legislation—indeed, the very significant lack of important procedures and safeguards in the legislation.

First, in a matter which is probably not unprecedented, but quite unusual, the Secretary has no voice in determining what the Board will do.

I just want to mention one other thing, and that is that the Administrative Procedure Act is not applied. That is also, if not unprecedented, highly unusual, and we would oppose it. S. 638 goes a long distance to resolve many of these problems. But we would hope that before Congress enacts any legislation that it take a good, careful and, might I say, long look at what OSHA is doing and what OSHA can do. It is important not to set up additional bureaucracies if we can help it.

Thank you, Senator.

Senator QUAYLE. Thank you very much, Mr. Berrington.

[The prepared statement of Mr. Berrington follows:]

STATEMENT OF THE AMERICAN INSURANCE ASSOCIATION

TESTIMONY OF CRAIG A. BERRINGTON
SENATE LABOR SUBCOMMITTEE OF THE
COMMITTEE ON LABOR AND HUMAN RESOURCES
CONCERNING
S. 79 - THE HIGH RISK OCCUPATIONAL DISEASE
NOTIFICATION AND PREVENTION ACT OF 1987
MARCH 9, 1987

American
Insurance
Association

The American Insurance Association is a national trade organization of casualty insurers.

Thank you Mr. Chairman. I appreciate the opportunity to be here today to discuss S. 79, the High Risk Occupational Disease Notification and Prevention Act of 1987. My name is Craig Berrington. I am General Counsel of the American Insurance Association ("AIA") and am presenting testimony on behalf of the AIA, the Alliance of American Insurers, and the National Association of Independent Insurers. Together, we represent property and casualty insurance companies which write approximately 85% of the workers' compensation insurance provided in the United States. I am accompanied by Tom O'Day, Associate Vice President for the Alliance, and William C. Aldrich, Vice President for Government Relations of the Hartford Insurance Group.

Mr. Chairman, workers' compensation is the product of one of the great reform movements of the 20th century. Its goal was to reduce litigation and to provide the certainty of wage and medical protection for America's workers. We are proud to have been an important part of that reform movement and to have as our primary concern the health and well-being of Americans on-the-job. We, therefore, support responsible measures that will further protect workers' health and assure them of necessary medical attention. Indeed, we were strong, early proponents for the enactment of the Occupational Safety and Health Act.

We are also in the position, Mr. Chairman, of seeing how legislation actually operates. We see the claims process up-close. We see the civil justice and workers' compensation systems up-close. We see the financial costs of legislation up-close, too, and are in the position of explaining to state regulators and policyholders the financial impact of legislation.

It is with our dual perspective on these issues that we, in the insurance industry, need to examine S. 79. Good intentions are important and we concur in the good intentions of S. 79. Workers need to know when their working environment is dangerous. They need to know it early. They need to be given instructions on protecting themselves. They ought to have necessary medical monitoring and, of course, necessary medical attention.

But good intentions are obviously not enough. Legislation needs to be carefully drafted. We must not fall prey to the notion that a problem is so important that shortcuts should be utilized, procedural safeguards ignored, scientific standards trimmed, and the impact on the judicial system left unexamined. We are pleased that S. 79 does address some of these concerns better than S. 2050, introduced in the last Congress. But more work needs to be done and, we believe, in certain key areas, some fundamental rethinking is in order. The Committee has already taken a great deal of thoughtful testimony, raising important questions about S. 79. I do not want merely to repeat that testimony, but wish to concentrate on specific aspects of the bill.

DETERMINATION OF AN OCCUPATIONAL HEALTH HAZARD

At the heart of the proposed legislation is the procedure by which perceived workplace hazards are turned into notifications. It is critical that this procedure be rigorous; that it be based on the very best scientific data and analysis; and that the use of notifications be limited to situations where the connection between an agent and an illness is scientifically clear. It is also important that the procedures contain sufficient flexibility to allow the notices to be tailored to meet the needs presented by each agent which is the subject of notification.

S.79 raises five specific problems in this regard. First, we believe that the two key definitions of "occupational health hazard" and "population at risk of disease" are not sufficiently clear. Second, we believe that it is improper to allow the Risk Assessment Board to act on the basis of just one study. Third, we are concerned about the type of studies that the Board can consider in making its determinations. Fourth, the lack of professional scientific review of Board determinations is very troubling and needs to be corrected. And finally, we are concerned about the rigidity of the notice requirements without regard to the potentially unique characteristics of the agents which are the subject of any specific notification.

The term "occupational health hazard" is defined to mean "a chemical, a physical, or a biological agent, or an industrial or commercial process, found in the workplace for which there is statistically significant evidence ... that acute or chronic health effects may occur in exposed employees." What is meant by "statistically significant" is not defined and not tied into "probability analysis," thus leading to uncertainty.

The definition of occupational health hazard also includes a parenthetical statement that causes us concern. That statement allows such a hazard to be found, even if there is only "one study conducted in accordance with established scientific principles." This approach, which allows the Risk Assessment Board ("Board") to go forward with proposed notification for countless numbers of workers, seems to allow the Board to select any study it desires that gives the results it wants. This concern ties back into the undefined term, "statistically significant," and provides the Board with more discretion than it ought to have. More guidance needs to be given not only to the Board, but also to the courts, which must have both the right and the tools to determine whether or not the Board is performing the functions for which it would be created. The "one study" approach falls far short of this type of necessary guidance.

In addition to our difficulties with the S. 79 "one study" approach, we are concerned that the type or types of studies that the S. 79 Board can consider is not defined. The bill does not specify whether these studies are to be epidemiological or clinical studies, or merely laboratory studies conducted with animal or tissue cultures. Further, the definition of "population at risk of disease" includes "... an employee population exposed to an occupational health hazard at intensities or for durations comparable to at least one study referred to in (the definition of "occupational health hazard")." A literal reading of this provision would mean that if workers were exposed to a hazard at the same level as mice used in an experiment, these workers would be in a "population at risk of disease." Obviously, this would not appear to be the result intended by this bill. It is used here merely to illustrate the need for clarity in the definitions used in S. 79 and the fact that this clarity has not yet been achieved.

Our fourth concern, as I have noted, relates to the lack of professional scientific review of the Board's decisions. We think that the impact on society of these notifications would be so great that we must err on the side of caution and care. A broad based review process should be used, not a narrow process insulated from other expert perspectives. In this regard, I think it's useful to contrast the insulated approach of S.79 with the approach taken in S.638, the Health Risk Notification Act of

1987, introduced by Senator Quayle, which requires the Secretary of Health and Human Services ("Secretary"), in consultation with the Director of the National Institutes of Health and the Director of the Centers for Disease Control, to appoint peer review groups to review studies and thus provide an essential check on the process. If the Board were to remain in S.79, such a peer review process would be as welcome in that bill as it is in S.638 and would help assure that an inappropriate Board determination does not become the basis for notification.

S.638 also requires the scientific peer review group to make recommendations whether the provision of notice to certain persons is required and, if so, the appropriate type and content of such notice. This emphasis in S.638 on tailoring each notice to meet the unique characteristics of the study upon which the notice is based is well-founded. Rather than emphasize the mass production of notices to meet an artificial quota, as is done in S.79, this individualized approach takes into account the different needs of different segments of the work force based on the type of exposure. The quota in S.79 of 300,000 notifications each year (or at the minimum 100,000) is truly inappropriate and, in our judgment, has no place in legislation devoted to the scientific process.

We are also concerned about the reach of S.79 to employees exposed to an occupational health hazard within 30 years of a notification. This time period is excessive and will prove to be both expensive and exceedingly difficult to administer. Just physically tracking down the names and addresses of employees who were exposed that long ago appears insurmountable. This task even comes after an employer's initial determination of who was doing what job around which occupational health hazard three decades ago. Instead of the impossible standard of the 30 year search, the legislation should provide a reasonable, obtainable goal. If it is determined that the notice must include former workers rather than being prospective only, the backward reach in time should be reasonable and one that can be obtained.

LIABILITY POTENTIAL

Since S. 2050 was introduced in the 99th Congress, some recognition has been given to the fact that there is a liability potential created by this bill. As a result, S. 79 contains some language designed to limit this liability. We are not yet convinced, however, that it is possible, with any language, to wall off the liability potential of this bill. Our concern is three-fold.

First, we believe, there will be intense pressure on the workers' compensation system to presume the work-relatedness of each particular individual's illness for which a general notification has been issued. Second, we are concerned that the actual notices will not be kept out of workers' compensation or civil proceedings. Third, we are certain that stress claims will be triggered by the notices. I'd like to discuss each of these points.

It is correct that language in S. 79 indicates that the notification of an employee does not constitute or in any way effect a claim for workers' compensation or for loss or damage arising out of the exposure. But once employees receive a notice endorsed and required by the federal government that they are in a population at risk of disease due to a workplace exposure to an occupational health hazard, it is logical to anticipate that great pressure will be put on the workers' compensation system to provide relief. Of course, a true occupational disease should be compensable under workers' compensation, but obviously only if it arises out of and in the course of employment. These conditions are met when the risk of contracting the disease is increased by the nature or condition of the employment. But care must be taken that the mere receipt of the notice does not replace the requirement of work relatedness.

Moreover, we believe that workers' compensation benefits should be the exclusive liability of an employer for a work related injury or disease. This is the historic basis of the workers' compensation system. And it is important that federal legislation not dilute it. If, however, an S.79 notification is allowed in a civil proceeding against an employer, S.79 has the potential of creating a whole new class of unwarranted intentional tort actions against employers who have already provided workers' compensation benefits. This will happen because each time the Board determines to issue a notification, it is likely to trigger a presumption in the minds of the triers of fact that may well be insurmountable in individual cases. Thus, regardless of efforts by an employer to protect employees, the mere fact that a hazard now subject to a notification was allowed into the work place by an employer will conceivably be sufficient to establish the requisite intent and thus seriously erode the concept that workers' compensation should be the exclusive remedy for workplace accidents and illnesses.

As noted earlier, we are mindful of the language in S.79 to address some of these problems, and we are also aware of the careful efforts to minimize liability potential which are contained in S. 638. Like S. 79, S. 638 provides that no claim for workers' compensation or for any action for personal injury, damages, or any other relief is affected. S. 638, however, goes further and provides that no finding or determination that an individual may contract a disease as a result of exposure to a hazardous substance shall constitute a legal basis for damages or for a compensation award nor be admissible in evidence in any such legal action. Similarly the provision for the actual notice itself shall not constitute the basis for nor be admissible in evidence in any legal action for compensation or damages.

While applauding, however, the additional steps in both S. 79 and S. 638 to wall off liability, it is our view that no legislation should be acted on by this or any Committee without an understanding of its ramifications on the workers' compensation and civil justice systems. We would suggest, therefore, the need for more study and consideration of the liability potential before rushing to enact this major piece of legislation. If this does not occur, then it is our opinion that future hearings will be conducted by this Committee similar to the ones already held on the asbestos problem and why the courts cannot cope with the flood of lawsuits there.

Even if we were able to prohibit the notices themselves from finding their way into the compensation and tort systems and becoming, on their own, the basis for claims, it is our belief that claims will escalate. In the workers' compensation arena, these claims will most likely take the form of stress claims. It is difficult to imagine that it would not be stressful to workers to receive a notice that they have been exposed to a substance in the workplace and that the exposure could result in an occupational disease. The frequency with which this stress would result in a disability or impairment in a workers' compensation sense is, of course, not known, but the potential for an onslaught of new claims is very great. Unfortunately, neither S.79 nor S.638, contains language to limit stress claims in these circumstances.

In this connection, a recent Washington Post article (February 20, 1987, p. B5) noted that the increase in stress claims is escalating the cost of workers' compensation. While the workers' compensation system clearly needs to adequately handle stress claims, it would be inappropriate to place into that system claims that do not arise from the workplace, but arise rather from a federally mandated notification process.

Finally, we agree that the notice required by the bill should not be relevant in determining whether a claim is timely under any applicable statute of limitations. It is critical that everyone understand that workers' compensation suits do not have to be filed as soon as notice is received.

Although we have felt the need to restate our views on the role of the workers' compensation and liability systems in general and their relationship to occupational disease in particular, we are hopeful that our views and the views of the bill's sponsors on this subject are not irreconcilable. We note the inclusion of the language contained in section 10(g) directed to some of these problems and are primarily concerned about the effectiveness of this language in the areas we have detailed. It is our understanding that it is the intent of S. 79 neither to add to nor subtract from a worker's current rights under either compensation or liability proceedings. We are not convinced that this is possible, but think that the inclusion of language to correct the problems we have enumerated would definitely assist in achieving that goal.

REVIEW PROCEDURES

Once the Board makes a determination that a class or category of employees fits the definition of "population at risk of disease," the procedures to implement this decision are dangerously expedited and the procedural protections inappropriately restricted. This statement is made based on five specific items contained in S. 79. These are:

1. The Secretary has no voice in what constitutes a population at risk of disease;

2. Final agency action must be completed within 90 to 150 days without regard to conflicting testimony presented at the hearing;

3. Procedures to hasten this action are provided, but none are granted to slow the process down, if warranted;

4. Administrative Procedures Act guidelines are not followed for judicial review; and

5. The requirements to obtain a stay of the notification procedures are not acceptable.

Each of these will be discussed individually.

The bill requires that, within 10 days of making a determination of a population at risk, this determination must be transferred to the Secretary of Health and Human Services. The Secretary is given no voice in this determination and cannot instruct the Board to reconsider its determination. Rather, the Board issues a notice of the proposed determination in the Federal Register. Then 45 days are provided from the day notice is published in the Register for the receipt of written comments and a mere 30 days from the date of the notice are provided before the hearing takes place. This is the one opportunity for the public orally to express its views on the proposal and for the Board to hear what other occupational disease experts think about its findings. Yet, only 30 days are allowed for the preparation of this testimony. If the study used by the Board is unfamiliar to other experts, there is very little time provided to prepare an analysis. This, in our opinion, reinforces the need and desirability for a peer review process as contained in the Quayle bill.

Moreover, just 45 days after this hearing, the Board must issue a final determination pursuant to the hearing record. This is a total of 75 days from the date the notice first appeared in the Register. The bill does provide that, in exceptional circumstances, this time period may be extended, but it may not exceed 150 days from publication in the Register. This forces the process and exalts speed over care. On the contrary, the result sought by the bill should be to have determinations based on the very finest scientific data and analysis. There should be no hint that the goal is to turn out notifications on a rigid time table.

Based on these comments, we also have to oppose the provision contained in section 4(c)(5) of S. 79 that allows any aggrieved person to bring a civil action for mandamus if the Board does not complete its final agency action within the 90 to 150 day time requirements. (It would appear that the bill only allows 75 days and not the 90 referenced in this section for this final determination.) This is a misuse of mandamus, which is not otherwise available for judgmental matters, but only for the most routine, ministerial acts of government. Moreover, no corresponding right to halt this process is allowed a party who thinks that a classification of "population at risk of disease" is being wrongly pushed through the Board. This emphasis on tight time requirements at the expense of careful consideration is unsupportable.

This emphasis on numbers reaches its most ludicrous point in the bill when the Board, as we noted earlier, is mandated to notify between 100,000 and 300,000 employees per year. Again, the emphasis on numbers and not on quality in the bill is indefensible, in our opinion.

The quick time tables mandated by the bill are also a problem when considered in conjunction with the judicial review provisions contained in section 5(g) of S. 79. Thirty days after a Board determination that a given class or category of employees is a population at risk of disease, judicial review is provided for any person adversely affected or aggrieved. The criteria for the court to use in determining whether or not to set aside a Board determination are based loosely, but not entirely, on the Administrative Procedures Act (APA). (5 U.S.C.A. 706.)

While the first four grounds in S.79 are very similar to the APA, the last two APA grounds are omitted in their entirety from S.79. These two, basically, are when the agency action is unsupported by substantial evidence or is unwarranted by the facts. The elimination of these two criteria and the deviation from the APA is improper and unsupportable. It is hard to discern a legitimate reason for it.

Further, the commencement of the proceedings described above do not operate as a stay on the Secretary's requirement to notify employees unless, as stated in section 5(g)(4) of the bill, "...the court specifically orders a stay based on a determination by the court that the complaining party is highly likely to succeed on the merits." Thus, unless the court determines that the Board acted in an arbitrary or capricious manner or with an abuse of power or in another manner described in the bill, the notification must be given to all affected employees while the parties pursue a final determination in court. This procedure is troubling. We would prefer that the bill not impose standards on the courts in these situations, but permit well developed principles of jurisprudence to be used in determining these issues.

EMPLOYEE TESTING, EVALUATION AND MEDICAL MONITORING

Section 9 of the bill sets out, among other items, the requirements for the testing, evaluation, and medical monitoring of notified employees. There is no guidance as to who selects the physician and exactly how this service is to be provided. For a small employer, in particular, who perhaps has no medical plan of any type, some guidance in this area is not only appropriate but necessary to prevent confusion in implementing the requirements of the bill.

There is some indication in section 9(c) that the employee is to have some choice of physician and that this physician's opinion is to be given more weight than that of the employer's medical representative. Further, the employee's physician alone appears to be given sole discretion in determining whether or not and, if so, for how long an employee is to be transferred to a less hazardous job, within the one year confines. If the employee's physician decides unilaterally that an employee is disabled and therefore can no longer perform his or her duties, the obvious result will be a claim for workers' compensation. If an employee truly has an occupational disease, the claim should be filed and the employee compensated.

The concern with the almost total discretion apparently given to the employee's physician is the potential for abuse. That workers' compensation and selection of physicians can be an area of wide-spread abuse was noted earlier during the discussion of stress claims and also was pointed out to this Subcommittee during hearings in the 97th Congress on amendments to the Longshore and Harbor Workers' Compensation Act ("Longshore"). (33 U.S.C.A. 901 et seq.) As a result of that testimony, procedural requirements and restrictions were placed on selection of physicians in Longshore. These were, at the time, agreed to by all affected parties and are contained in public law 98-426. While the Longshore procedures may not be an entirely apt model for a notification bill, the primary importance lies in the recognition in Longshore of the problem.

For example, to prevent "doctor shopping" under Longshore, an employee may not change physicians after his initial claim unless the employer, insurance carrier, or Department of Labor hearing officer has given prior consent for the change. If the employee unreasonably refuses to submit to an examination by a physician selected by the employer, payment of compensation may be suspended. These restrictions on unilateral decisions by an employee's doctor in a compensation setting might also work well in situations where a transfer to other work is being contemplated.

As the Committee knows, choice of physician varies greatly in the states. Almost half allow either employer choice or employee choice only from an approved list. Additional requirements and limitations also vary but there is ample precedent for limitations in this area.

NEED TO CONSIDER THE OSHA HAZARD COMMUNICATION STANDARD

In addition to the concerns set forth in this statement about S.79, we think that discussions should also focus on whether any additional government involvement in the notification of workers exposed to a workplace hazard is necessary at all. One variation of providing this notice was just recently implemented by the Department of Labor through the Occupational Safety and Health Administration. Known as the Hazard Communication Standard or "Right-to-Know-Standard," it requires chemical manufacturers and importers to evaluate the hazards of each chemical they manufacture or import; label each shipped container of a hazardous chemical; and prepare a material safety data sheet ("MSDS") designed to protect workers from these hazards. An MSDS must include the acute and chronic health effects of the chemical, as well as the signs and symptoms of exposure, and any medical conditions which may be aggravated by exposure.

In addition, the Hazard Communication Standard contains requirements for all manufacturers. Each must write and implement a hazard communication program; label all containers in the facility; maintain an MSDS and provide their employees with access to them; and train workers about the hazards, how to avoid them, and how to use the information made available under the standard. OSHA has announced its intent to expand this standard to all workers exposed to hazardous chemicals.

We applaud this type of effort to notify workers of the potential hazards they face in the workplace. We are also aware of the criticisms of some that the standard does not go far enough because it does not cover former employees or state and local governments. Rather than debate these criticisms, let me state simply my disappointment that some are not willing to allow this standard, the entirety of which has been enforced only since May 25th of last year, an opportunity to work and to evaluate its effectiveness before rushing to enact new legislation.

CONCLUSION

After much thoughtful discussion, we have concluded, Mr. Chairman, that we must oppose S.79, even though we support the concept of workers receiving notification that they are in a population at risk of disease.

The proposals contained in S. 638 are further evidence that new ideas and refinement of the concept of worker notification will and are leading to a better legislative work product. Stronger language to wall off liability, use of epidemiological studies, scientific peer review groups, and tailor made notices were all discussed in this Statement and are contained in S. 638. These and other ideas presented during this hearing need time for careful consideration and analysis.

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Senator QUAYLE. Let me ask a couple questions. Given your experience in the workers' compensation programs, what do you think the impact of S. 79 would be on these programs?

Mr. Berrington?

Mr. BERRINGTON. I think, Senator, that it would have a massive impact. It is not easy to predict it right now, but clearly, the stress issues, these stress claims which I mentioned earlier, will be coming from the notification process itself; secondly, the fact that individuals getting notification will be in a position—indeed, I think they will be urged in some cases—to file claims in order to protect their situation; and thirdly, we believe that there will be great pressure on the workers' compensation system to provide relief. Notification has been put out there. Even if the disease is prevalent in the population as a whole, which most of these are, there will be great pressure to have this workers' compensation system, which is available, to provide the relief. And as the insurance system and insurance pricing reflects what is going on in society, we should expect that these costs will be reflected in costs throughout society.

Senator QUAYLE. Mr. Tatum, do you have anything to add to that?

Mr. TATUM. Yes, Senator. I think I certainly agree that it would increase the amount of litigation in the workers' compensation system. I think indeed most attorneys, if their client receives a notification that they have had such exposure and maybe at risk, out of the excess in caution most attorneys take in determining whether or not to file a claim, they would do so, and then worry later about whether or not the claim may or may not be compensable.

I would also agree that just a notification itself would give rise to, or may be give rise to, numerous stress claims and possibly some psychological claims, which we see a number of in the workers' compensation systems today.

Senator QUAYLE. S. 79 requires medical monitoring. I am sure you are aware of that. Doesn't this really assume causation? Do you think this will become a new Federal standard of liability for occupationally-related health costs?

Mr. BERRINGTON. I am hesitant, Senator, to try to anticipate others' agendas, but certainly, it has that ring to it. I suspect, though, that those who have that agenda might find that the implementation of S. 79 would cause so much chaos and difficulty that their agenda would be derailed.

I was in the situation, Senator, of having to pick up the pieces in the Federal Government after the 1977-1978 Amendments to the black lung statute, which Congress then corrected in late 1981—but not until after the whole notion of that legislation came into disrepute because good intentions ran wild; good intentions outran the drafting skill and the sense of caution which ought to pertain in all of this legislation.

But I think it would not be unusual, or it would not be surprising, if in the minds of those who have drafted S. 79 that this was just the first step toward full-scale occupational disease legislation.

Senator QUAYLE. Mr. Tatum, do you see that as a distinct possibility, that we are going to first of all establish a Federal liability standard, and then next, we may be certainly paving the way for a Federal occupational disease law?

Mr. TATUM. Senator, in my opinion, we may not only be paving the way for a Federal occupational disease law, but a Federal occupational disease system to administer that law, which our State systems have always opposed.

Senator QUAYLE. So you see this as a very real possibility in the direction that this is going?

Mr. TATUM. I certainly do. The entire bill addresses the subject, occupational disease, regardless of which provision you look at—I mean, the entire bill is built around occupational disease, and that is a major part of the existing workers' compensation systems in all the States today.

[Additional material supplied for the record follows:]

UNIVERSITY OF CALIFORNIA, IRVINE

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March 18, 1987

Ms. Mary McGrane
Senate Labor Subcommittee
Minority Staff
United States Senate
Washington, DC 20510

Dear Ms. McGrane:

I enclose a letter addressed to the Subcommittee concerning health risk notification of workers. I regret not being able to attend the hearing or to answer questions. Although there are many specific points in the bills that I could comment on, I thought I should restrict my written comments to the issues I've thought most about. I hope the ideas will be helpful.

Sincerely yours,

James L. Whittenberger

James L. Whittenberger, M.D.
Professor and Chair, Department of Community and Environmental Medicine
Director, Southern Occupational Health Center

JLW:cmj

Enclosure

Mr. Chairman and Members of the Subcommittee:

I am James L. Whittenberger, M.D., Director of the Southern Occupational Health Center, University of California at Irvine and Los Angeles. Thank you for the opportunity to comment on health risk worker notification, specifically in reference to Senator Quayle's bill (S.638) and Senator Metzenbaum's bill (S.79). These remarks are my own, and are not intended to reflect the views of the University of California or any other institution.

Notification of health risks associated with the workplace is a deceptively simple concept, just as making the public aware of health risks from behavioral characteristics such as smoking, and from exposure to other kinds of environmental pollution, such as contamination of food, water, and air is deceptively simple. In fact the issues associated with notification are very complex and important. Some of these are dealt with in both bills, explicitly or implicitly.

One set of complex issues is the scientific basis of the health risk assessment. Although it is conceivable that one study can provide persuasive evidence that a notifiable risk exists (as specified in S.79), this will rarely be the case. Flexible guidelines and criteria, as specified in S.638, would be preferable. Scientific evaluation and judgment need to be applied when risks are inferred or calculated from different kinds of studies, such as industrial hygiene surveys, epidemiologic studies, or toxicologic information from human or experimental animal exposures. A strong argument for flexibility can be made by a hypothetical example which would trigger individual notification when the risk of death is deemed to be increased by 30% due to a workplace exposure. An increase of 30% over a high baseline rate such as that of heart disease or lung cancer would be a far more serious health risk than a 30% increase of mortality rate from a rare condition.

Another complex set of issues relating to notification is the interplay of ethical, public health, and civil rights objectives with other social and economic issues. Some argue that whenever epidemiologic studies are done, the potentially affected workers should be individually notified, independent of whether the results of the study show increased risk. I accept this as an ideal, but it ignores the costs of individual notification, which could become astronomical and would impinge on the priorities of other socially desirable goals, such as doing more risk identification research.

Closely related issues are determination of what is a significant risk, and should workers be notified if no effective early disease detection method is available? Also, what facilities would be available for counseling of notified workers, and what treatment facilities would be available to those in whom the disease has occurred? In my opinion these interrelated ethical, practical, and economic issues support the argument for graded notification responses, using well-established notification methods in most cases, and reserving costly individual notification for populations in which the health risk is considered high and where medical surveillance and early treatment can be effective.

A further complex and important set of issues related to worker notification is not addressed in either bill--the problems associated with risk perceptions and risk communication. The magnitude of these problems for environmental health and occupational health has been increasingly appreciated in the past decade, highlighted by the fiascoes in relations of governmental agencies with the community at Love Canal. These problems are now acknowledged by Federal agencies and state and local governments, and there is increasing awareness of the need for research, education, and improvements in ways of dealing with problems in risk perception and health risk communication. Some examples of current research questions in risk communication are the following:

How can people be motivated to find out if they are at risk?

How can we improve communication of low probability health risks?

How does the source of information influence risk perception?

How can scientific uncertainty be effectively communicated to the public or the worker?

The research needed on risk communication as well as research needs to improve health risk assessment and methods of medical surveillance persuade me that passage of either S.79 or S.638 would require additional resources. Even greater resources would be demanded to provide screening, counseling, and medical diagnosis and treatment facilities, which are almost obligatory following worker notification. Authorization of some funding for these and related purposes is provided by Senator Metzenbaum's bill but not by Senator Quayle's bill.

Finally, I believe that NIOSH's track record in worker notification is a very good one, that their pilot studies of individual worker notification have been thoughtfully and competently done, and that implementation of their Board of Scientific Counsellor recommendations for individual worker notification is proceeding effectively. I believe NIOSH will be well prepared to implement their part in whatever legislation is passed.

RMA
RUBBER MANUFACTURERS ASSOCIATION
1400 K STREET, N.W. • WASHINGTON, D.C. 20005 • (202) 682-4800

March 6, 1987

The Honorable Dan Quayle
Subcommittee on Labor
Senate Committee on Labor and Human Resources
U.S. Senate
Washington, D.C. 20515

Dear Senator Quayle:

Please find enclosed a letter from RMA's President, Donald G. Brotzman, stating RMA's position on S.79, "High Risk Occupational Disease Notification and Prevention Act of 1987."

RMA respectfully requests that the enclosed letter be considered our testimony/comments for the official record on S.79 which is before the subcommittee.

Although the RMA is opposing S.79 as proposed, we are most willing to discuss the important issue of appropriate worker notification at any time that is convenient to you and your staff.

Sincerely,

Frank T. Ryan

Frank T. Ryan
Vice Preident
Government Relations

FTR/mrs
Enclosure

RUBBER MANUFACTURERS ASSOCIATION
1400 K STREET, N.W. • WASHINGTON, D.C. 20005 • (202) 682-4826

OFFICE OF THE PRESIDENT

March 5, 1987

The Honorable Dan Quayle
U.S. Senate
Washington, D.C. 20515

Dear Senator Quayle:

The RMA is a national trade association representing approximately 200 companies engaged in the production of tires and other rubber goods. I am writing to voice concern over pending occupational disease notification legislation, S.79, which is before the Labor and Human Resources Subcommittee on Labor. It is the position of RMA that this legislation is unnecessary and inappropriate for the following reasons:

1) The OSHA Hazard Communication Standard sufficiently provides for notification to current employees about occupational hazards to which they are exposed and their potential effect on worker health. This Standard went into effect on May 25, 1986, and is the most comprehensive rule promulgated by OSHA. Having been in effect for only nine months, it should first be evaluated as to its effectiveness and improved, if necessary, before Congress creates an entirely new program. With regard to former employees, OSHA's Access to Employee Exposure to Medical Records (CFR 1910.20), which became effective August 21, 1980, requires employers to maintain and provide current and former employees access to records of employee exposure and records of medical surveillance.

2) OSHA inspections evaluate hazards and provide enforcement in those instances where employees are found to be at risk. In addition, NIOSH conducts routine health hazard evaluations which focus on employee hazards. Furthermore, employees and their representatives are made aware of these findings.

3) In addition to governmental programs, industry has discharged its responsibility by recognizing, controlling and eliminating potential employee exposure to occupational hazards. The risks for failing to do so are exemplified by the black lung benefits program, the asbestos litigation crisis, as well as spiraling health care and product liability costs.

4) Unnecessary legislation of this type would create an overlapping, unwieldy, expensive, new bureaucracy within the Department of Health and Human Services which could rival and clash with the Occupational Safety and Health Administration.

5) Methods to enact such legislation establish insufficient and unclear criteria for identifying employees at risk who should be notified. They are also premised on a greater technological feasibility and effectiveness from medical monitoring and screening than those procedures have been able to deliver. The bill's requirement that no fewer than 100,000 employees be notified each year is arbitrary and undermines any attempt to maintain a "statistically significant" determination of populations truly at risk and deserving of notification. Notifying workers incorrectly that they are at risk of contracting a disease would be unjustifiably distressing.

6) The cost of locating, notifying and counseling each affected worker, and of establishing at least one health center per state would be staggering.

7) The legislation as proposed would greatly increase the cost of health insurance and workers' compensation insurance, and it would serve as a catalyst for unnecessary employee lawsuits filed against employers. The impact of this liability on the already existing liability crisis would be enormous.

8) Overall, this legislation will have a significant anticompetitive impact upon the business sector, particularly at a time when we are searching for solutions to the trade imbalance problem.

RMA supports the belief that employees who are at risk of occupational disease should be informed so that preventive measures can be taken. This goal is achievable with existing programs to the extent that the adoption of S.79 is unnecessary. I urge you to consider all of these points carefully and oppose S.79 when it is considered by the Subcommittee.

Very truly yours,

Donald G. Brotzman

Donald G. Brotzman

mrs
cc Senate Committee on Labor
and Human Resources

STATEMENT FOR THE RECORD

SUBMITTED BY

THE STANDARD OIL COMPANY

"HIGH RISK OCCUPATIONAL DISEASE NOTIFICATION AND PREVENTION ACT OF 1987" (S. 79)

Overview/Position

The Standard Oil Company appreciates the opportunity to present our comments on the "High Risk Occupational Disease Notification and Prevention Act of 1987" (S. 79). Standard Oil is an Ohio corporation engaged in a broad range of oil and gas, natural resource, chemical and industrial product businesses, employing approximately 40,000 people.

The Standard Oil Company strongly supports the goal of protecting workers and preventing occupational disease. Our companies are in compliance with OSHA workplace standards; including the Hazard Communication Standard and the medical surveillance programs of the individual OSHA standards. Employees potentially exposed to agents for which no OSHA standard exists, but for which the Company believes medical monitoring is prudent, are offered such medical programs.

Standard Oil has demonstrated its dedication to a healthy workplace by implementation of policies ensuring the protection of employee health and promoting employee safety. The Company provides many employees, based upon their age, periodic health evaluations unrelated to potential workplace exposures, as preventative medical programs. Employee health education information and fitness programs are also offered. Finally, the Company has taken a strong position for a healthy workplace with initiatives against smoking and substance abuse by employees.

We strongly believe that where studies indicate an adverse health effect from materials or physical agents, individuals exposed to harmful concentrations must be informed. In fact, Standard Oil, in the past, has taken steps to notify workers and consumers about the potential health effects of our products and worker protections, despite the often detrimental effects of such announcements in the marketplace.

In view of our commitment and dedication to worker health and safety, Standard Oil supports the prevention of occupationally-related illness in employees.

However, we believe the mechanisms proposed in S. 79, as currently drafted, are seriously flawed and will not achieve the stated goal of disease prevention. Furthermore, if enacted in its current form, S. 79 would burden U. S. industry and the public with the costs of a new notification bureaucracy leading to individual anxiety and unfounded litigation.

S. 79 uses an unsound approach to the determination of populations at risk; does not provide for sufficient expertise for sound decision making; lacks adequate peer review and public comment period; establishes a notification quota which is inappropriate and which would undermine the credibility of the notification program; creates a new, expansive and costly bureaucracy which would duplicate many existing programs within other agencies; has the potential to mandate inflexible standards as opposed to more effective guidelines relative to medical surveillance and monitoring; lacks necessary provisions for judicial review; and lacks adequate protection against unwarranted litigation and compensation claims.

Passage of S. 79 and implementation of its current provisions will result in significant regulatory and program duplication, massive economic burdens on the public and industry in this country, jurisdictional conflicts between federal agencies, intolerable escalation in frivolous tort actions against businesses, and a basic threat to the viability of many smaller U. S. businesses.

The focus of any federal legislation in this area should be directed to strengthening the many programs already currently in place under federal agencies, and ensuring that workers (both current and former) and the public are informed promptly of substances identified by scientifically accurate epidemiology studies which cause adverse human health effects.

Standard Oil encourages Members of Congress to oppose S. 79 and to carefully consider the principles outlined in our following comments and the alternative proposal, S. 638, introduced by Senator Quayle. Congress should review the extent of current regulations and policies in the area of worker disease notification and prevention and proceed with deliberate care in the development of any further federal legislation concerning worker disease notification.

Specific Concerns With S. 79

Our specific problems and concerns with S. 79 are as delineated below:

1. S. 79 uses an unsound approach to the determination of the "population at risk" which would result in notification of workers who are not really at increased risk of occupational disease. Notification could be triggered by only one "statistically significant" animal or laboratory study indicating that acute or chronic health effects may occur in exposed employees. This notification trigger provides inadequate assurance that several critical epidemiological principles are properly addressed (e.g. strength of association, dose response relationships, biological plausibility, attributable risk, temporal relationships, significance of conflicting or negative studies, the role of contributing causal factors, the extent and seriousness of risk, and consistency of evidence).

2. The notification quota contained in S. 79 (100,000 to 300,000 employees per year) is inappropriate and a complete and unjustified departure from scientific principles. The actual number of workers requiring notification could be higher or lower and should not be established arbitrarily prior to the scientifically-valid determination of the "population at risk". Furthermore, notification quotas and targets undermine the credibility of a scientifically-based notification process and run the risk of generally being ignored by the recipients of the notification. Workers or former workers, who in fact are not at risk but were improperly notified in order to meet a notification quota, could:

    - be subject to unnecessary and unduly expensive medical surveillance;
    - sustain unnecessary emotional stress from misclassification of risk; or
    - initiate unfounded tort liability and compensation claims.

3. S. 79 does not provide sufficient expertise for sound decision-making. For example, the Risk Assessment Board consists solely of Public Health Service employees with no expertise from industry, labor, or academia. The Board would, therefore, have no representation from professionals outside of the government. In addition, the

provisions for expert peer review of the findings and decisions of the Risk Assessment Board are lacking and an insufficient public review and comment period is provided.

4. The attempt of S. 79 to insure scientific validity to epidemiological studies used as the basis for notification is inadequate because ill-defined standards are established in lieu of general guidelines. Standards infer inflexible rules which, when applied to every study routinely, may fail to be applicable to specific studies. In contrast, guidelines infer general principles underwhich one can consider the scientific merit of diverse study protocols. There are already acceptable guidelines developed by scientifically respected work groups and federal agencies which could be used in S. 79: e.g. (1) Report of the Subcommittee Counselors, February 15, 1986; (2) Guidelines for Documentation of Epidemiological studies, American Journal of Epidemiology, 114, 609-613, 1981; (3) Guidelines for Carcinogen Risk Assessment, Federal Register, 51, (185), 33991-34053, 1986; (4) Chemical Carcinogens. A Review of the Science and Its Principles, Federal Register, 50(50), 10372-10442, 1985.

5. Some of the requirements of S. 79 for informing employees of health hazards would duplicate existing programs under EPA's Office of Toxic Substances, OSHA's Hazard Communication Standard, numerous individual State Right-To-Know laws and the Mine Safety and Health Act. In addition, similar functions exist in the Disease Registry (ATDSR), located within the Center for Disease Control, under EPA provisions mandated under CERCLA (1980) and SARA (1986). It is important to remove such overlap to avoid the time and costs associated with duplication of efforts.

6. The certification of employers to conduct notification of "populations at risk" of former or existing employees is unclear in S. 79 with respect to whether or not the employer may elect to accept or decline this responsibility. This area of the bill needs to be clarified to allow employers who wish to notify existing or former employees the flexibility to do so, and the right to access necessary governmental records.

7. S. 79 directs the Risk Assessment Board to first designate employee "populations at risk" likely to benefit from medical surveillance or health counseling. As noted

above, guidelines rather than standards should be established by the Board, and latitude should be provided to the employer's licensed medical professionals to decide what medical procedures or tests would be deemed useful in the medical surveillance program. Developing technology not yet in universal use or highly specialized tests, should not be mandated. Furthermore, costly screening programs that fail to detect diseases sufficiently early to alter outcome, or tests that detect disease for which no medical intervention is feasible, do nothing to prevent illness. S. 79 also fails to ensure employee cooperation with employer efforts towards appropriate medical monitoring, nor does the bill assure employer access to relevant employee medical information to assist with preventive medical measures.

8. The standard for judicial review in Section 5 is based on "arbitrary and capricious" rather than the "substantial evidence" test. This basis for judicial review, in lieu of evidentiary fact, is inappropriate considering that the Risk Assessment Board's findings and impacts are based on evidentiary and material fact.

9. As a consequence of the arbitrary and unscientific basis for identifying "populations at risk", the bill would lead to substantially increased and unwarranted litigation and compensation claims.

In view of the above concerns, The Standard Oil Company opposes enactment of S. 79 as currently drafted. Because of the high costs, both direct and indirect, associated with federal legislation in the disease notification area, we urge Congress to use careful deliberation on this issue. Federal legislation, if any, must be designed which only notifies those persons truly at risk of an occupational disease who will benefit from such notification. In addition, sufficient safeguards must be enacted to prevent the notification from being misused in any subsequent legal proceedings. As currently structured, S. 79 does not achieve any of these critical requirements.

Suggested Approach To Worker Protection And Notification

Any health risk notification program should be founded on established, approved and scientifically sound principles. To this end, inclusion of the following epidemiological concepts are essential: the statistical reliability of the human study test results; the significance of the human health risk; the duration and intensity of exposure in the study; the consistency of all evidence indicating positive findings; the medical benefits that might result from notification; the potential effects and benefits of failing to provide notice; the potential effects of providing incorrect notice; and specific circumstances under which the results of the study justify notification outside of the population studied.

The key components of any federal notification program should be based on the following important factors:

Significant scientific evidence, including epidemiological studies and other relevant information rather than merely the results of only one study.

- Notification decisions should be at the discretion of acknowledged and experienced scientists and should incorporate adequate peer review, public comment, and other rulemaking procedures.

- Safeguards to avoid and prevent indiscriminate and erroneous notification.

- Adequate protective measures to avoid an onslaught of unwarranted tort actions and workers compensation claims.

Standard Oil's Experience With Employee Identification And Notification

Employer cohort determination and notification represents a tremendous undertaking, both in resources and in time. The Standard Oil Company's experience with identifying 2,000 employees, 1,500 of which were former employees for a plant started in the 1960s, has shown that many manmonths of effort are required to simply identify the appropriate persons within the cohort. These activities required the assistance of the Social Security Administration (SSA) for the purposes of acquiring worker identity information. It often takes SSA in excess of six months to respond to these requests. Once this information has been obtained, exhaustive review is required to extract only the appropriate employees from extensive and often duplicative listing of names.

Use of the SSA for personal identifiers is a common tool used in epidemiology. If many companies were required to initiate similar requests to SSA because of mandated notification, the increased burdens on SSA could very well lead to extensive and unpredictable delays in securing needed information to support employee identification and notification.

Once the cohort is identified, locating the employees (in particular, former employees) presents another extremely difficult, time consuming and expensive task. Certainly, a number of former employees may remain active on company books through continuation of medical and benefits programs. However, many will be lost to tracing because of geographical relocations. Locating individuals who have completely severed relations with an employer, presents a formidable and sometimes impossible challenge.

A prudent approach to ensure an effective and timely notification process would involve federal notification with an option for individual employers to undertake notification activities on a voluntary basis.

Additional major problems in identifying and contacting all persons ever employed in a specific facility and exposed to a specific agent, from our experience, are discussed below:

1. Identifying specific employees: The major sources used to identify employees, current or former, are the personnel record systems and benefits programs within each company. Personnel record systems may not be centralized and may not be computerized. Benefits programs identify only those employees receiving current benefits. Business operations historically have been sold with all records or conversely acquired with incomplete or non-existent records. Employees who leave the company before being eligible for company health and retirement benefits are usually extremely difficult to locate.

2. Identifying exposures to specific agents: Agents recognized as being potentially hazardous today, formerly may have been considered innocuous and, therefore, records of potential exposure to such agents often are incomplete or non-existent. These agents may have comprised only a small or transient part of the production process, with only a few employees in a plant actually potentially exposed. The employee records at the facility, however, may not identify those specific exposed employees.

3. Locating employees for notification: Notification of previous employees requires two steps: (1) verfication of vital status, and (2) determination of current address. The former must be provided by the SSA, while the latter may be available only from federal agencies (e.g., SSA, the Internal Revenue Service) or state agencies

(e.g. the Motor Vehicle Registration). These data bases for current addresses are generally not accessible by employees.

A prudent and expedient approach to worker notification would involve federal notification using the various data bases available to it with an option for individual notification by an employer on a voluntary basis.

Senator Quayle's Alternative Bill (S. 638)

Senator Quayle has introduced alternative legislation, S. 638, which offers significant improvements over S. 79. In particular:

- The Secretary of Human Health and Services and the Director of The National Institute of Safety and Health are directly involved in the development of procedures governing the efficacy of determination and notification of populations designated to be at risk of contracting occupational disease.

- While notification of former employees is primarily defined as the responsibility of the federal government, cooperation is fostered between the government and private employers which will permit those companies, who so desire, to notify their former employees.

- More extensive peer review procedures are incorporated which permit access to study results indicating any potential risk of disease.

- Protection against the use of the notification in any subsequent legal proceedings is addressed in a definitive manner.

Standard Oil is still assessing S. 638 and would appreciate the opportunity to provide substantive comments on that legislation at an appropriate later time.

Summary

In view of the above concerns, The Standard Oil company opposes enactment of S. 79 as currently drafted. Because of the high costs, both direct and indirect, associated with federal legislation in the disease notification area, we urge Congress to use careful deliberation on this issue. Federal legislation, if any, must be designed which only notifies those persons truly at risk of an occupational disease who will benefit from such notification. In addition, sufficient safeguards must be enacted to prevent the notification from being misused in any subsequent legal proceedings. As currently structured, S. 79 does not achieve any of these critical requirements.

The Standard Oil Company encourges Members of Congress to oppose S. 79 and to carefully consider our comments and the principles outlined in the alternative bill introduced by Senator Quayle (S. 638). We urge deliberate care in the development of any federal legislation concerning worker disease notification.

The Standard Oil Company appreciated the opportunity to provide our views on this most important issue.

TESTIMONY OF
GEORGE L. CARLO, PH.D.
OCCUPATIONAL EPIDEMIOLOGIST

GEORGE CARLO & ASSOCIATES, INC.
701 WEST PARK AVENUE
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ON
S. 79
THE HIGH RISK OCCUPATIONAL DISEASE
NOTIFICATION AND PREVENTION ACT OF 1987

BEFORE THE
LABOR SUBCOMMITTEE
OF THE
SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES

MARCH 19, 1987

Mr. Chairman and Members of the Subcommittee.

I am pleased to have this opportunity to comment on S. 79, the High Risk Occupational Disease Notification and Prevention Act of 1987. My name is George Carlo, and I am an epidemiologist who specializes in the study of occupational diseases. I currently hold faculty appointments at both the George Washington University Medical Center and the State University of New York at Buffalo School of Medicine, and am president of George Carlo & Associates, Inc., a health and environmental issues consulting firm based here in Washington. I previously was a member of the faculty at the University of Arkansas for Medical Sciences, served on Arkansas Governor Bill Clinton's Hazardous Waste Technical Advisory Committee, and was Research Leader in Epidemiology for the Dow Chemical Company. In my career I have conducted epidemiological research for and under the auspices of organized labor, government and private industry. I am here today as a public health professional and would like to speak to you with regard to the need for a practical and workable approach to meeting the important goals contemplated by S. 79, those goals being the prevention of occupational disease in this country.

My comments, which are based on my practical experience, fall into three general categories: the first involves the general framework within which a program designed to enhance the occupational health of workers should lie; the second involves the need to have a strong scientific and ethical base upon which to build such a program; and the third involves the nuts and bolts of making such a program work.

The general framework. Occupational health surveillance has made tremendous strides in the past decade and has evolved as a sophisticated melding of technologies from fields as highly diverse as analytical chemistry and medical genetics. When implemented properly, state-of-the-art occupational health surveillance is effective in reducing the impact of workplace hazards; however, because of its complex, multidisciplinary nature, it is extremely expensive and difficult to implement. For this reason, I believe that the establishment of a new government program to start, in effect, from scratch in attempting to attain the goals of S. 79 is ill advised. The only practical way to move forward in delivering improved occupational health is to build on the programs already in place in government, industry, and organized labor. We simply do not have the time or the resources to re-invent this wheel.

Within government, the Occupational Safety and Health Act is a logical starting point. The focus of OSHA inspection programs is primary prevention or the elimination of hazardous workplace exposures. The hazard communication standard under OSHA is an attempt to effectuate secondary prevention, that is, intervention after exposures are sustained. The stated purpose of S. 79 is an extension of this concept of secondary prevention.

Many companies within the private sector have sophisticated surveillance systems which actually go beyond the monitoring and notification programs contemplated by S. 79. And they work! A widely publicized recent example involves a study sponsored by Digital Equipment Corporation and conducted by scientists from the University of Massachusetts. The study was initiated after employees expressed concern regarding exposure to a workplace chemical. After only preliminary results were in, management not only notified employees regarding the findings but provided them with the option to transfer to other work areas.

Organized labor also has been active in developing occupational health programs. Efforts by the United Auto

Workers to embark on cooperative research and monitoring efforts with the automakers through joint health and safety committees are both laudable and progressive.

The seeds for progress have been planted in all three sectors, and it makes sense to me that every effort should be made to encourage the continuation of programs such as those just described. Toward this end, I urge you to shift the focus of the program to be implemented under S. 79 away from establishing a new government bureaucracy toward cultivating and encouraging activities already in place under OSHA, within industry, and within organized labor. I would suggest that mechanisms be put in place that would allow industry and labor to gain approval for implementing their own occupational health surveillance programs which should include provisions for notification, monitoring, and other activities implied under S. 79. The government-run programs under OSHA should be focused on monitoring the approved programs and on covering those industries and companies which cannot or choose not to develop their own programs. A self-policing advisory board staffed by professionals from approved non-government programs might also be a good idea. Such a shift in focus would be a significant step toward accomplishing the goals of S. 79.

The scientific and ethical base. Whether the programs are based in industry, labor, or government, good science and ethical standards in implementation are critical. S. 79 retains language which absolutely defines a "population at risk" as an employee population exposed to an occupational health hazard for which there is "statistically significant evidence," based on at least one study, that acute or chronic health effects may occur when such exposure occurs at intensities or for durations comparable to that one study. As an epidemiologist, I find it difficult to interpret any one study in a vacuum as it is necessary to consider the wealth of scientific evidence in evaluating the meaning of any research. The "statistically significant" trigger for notification, based as it is in S. 79 on any one study, is likely to lead to arbitrary decisions with respect to notification and follow-up.

In addition, this vague threshold for action is impractical. In Attachment A, I have listed several categories of individuals who could be targeted for notification under S. 79. Among the occupational groups are: professional and managerial workers with respect to melanoma; those involved in sedentary jobs with respect to colon cancer; and any professional or technical worker with respect to lymphoma. I believe all members of the Subcommittee would receive some sort of notification under these criteria.

In epidemiological terms, a "statistically significant" trigger based on one study will result in a high rate of false positives in the notification process because "statistically significant" is dependent on factors such as sample size which, in turn, are independent of biological significance. For this reason, peer review of the entire notification and follow-up process is essential.

Notification should not be taken lightly, as individuals who receive a notification are likely to take some action based on it. With notification comes a responsibility for follow-up, and in many cases effective follow-up and the implementation of preventive intervention can only be accomplished in the workplace; this is another reason why emphasis should be placed on programs that are run outside government. The government is not, and probably will never be, in a position to take upon itself the responsibility and expense of delivering sound occupational health programs to the workers of this country. Going half way with an issue as important as this will do more harm than good.

Because in many cases there may be no effective intervention possible, peer review within the framework of S. 79 must go beyond the assessment of risk to recommendations for preventive intervention. I urge the Subcommittee to examine the model for interaction between the Agency for Toxic Substances and Disease Registry and the Environmental Protection Agency established under the Superfund Amendments and Reauthorization Act of 1986. Such a collaboration between government agencies might be appropriate under S. 79. It also strikes me that ATSDR already has in place the personnel and capabilities contemplated for the Risk Assessment Board described in S. 79.

Finally, notification should not focus only on the bad news but should also include good news. Well run surveillance programs can provide information confirming the safety of industrial operations. I have had the opportunity to sit on the other side of the desk and inform workers of the results of studies we have completed, and, believe me, they deserve and welcome the opportunity to be able to breathe a sigh of relief once in a while. In my experience, workers are not only able to grasp the significance of epidemiological studies but are able to evaluate them with respect to how they might impact their own situation. Again, I believe that the only practical way to allow for reasoned notification and communication of results of surveillance activities is to build on existing programs where certain levels of trust have been developed.

The nuts and bolts. Effective, state-of-the-art occupational health surveillance of the type necessary to meet the goals of S. 79 will be expensive, and much more so than the $25,000,000 per year allotted in under the bill. In Attachment B, I have developed disease specific cost estimates for medical monitoring as contemplated under S. 79. The models and the costs are based on the actual types of tests which would be necessary to adequately follow groups after they have been notified. The follow-up protocols are sophisticated and involve considerable clinician contact. In Attachment C, I present total estimated costs for notification and follow-up of 50,000 workers for five selected diseases. It should be noted that medical care costs associated with positive disease diagnoses are not included, nor are indirect costs of likely litigation and workers' compensation claims derivative of the notification and follow-up program. Nevertheless, to meet the quota of

100,000 workers notified per year as described in the bill, the cost in the first two years will approach $383,000,000.

Mr. Chairman, the concepts underlying S. 79 are important and its goals are laudable. However, the success of this program in improving the occupational health of the American workforce will depend on how well it is implemented. I urge you to consider the practical aspects relative to implementation which I have outlined here.

Thank you.

ATTACHMENT A

TESTIMONY OF
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OCCUPATIONAL EPIDEMIOLOGIST

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ON

S. 79
THE HIGH RISK OCCUPATIONAL DISEASE
NOTIFICATION AND PREVENTION ACT OF 1987

BEFORE THE
LABOR SUBCOMMITTEE
OF THE
SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES

MARCH 19, 1987

The following tables were derived after a cursory review of recent issues of the American Journal of Epidemiology and the American Journal of Public Health. The tables present examples of associations reported where at least a 30 percent excess of disease was associated with a particular exposure (i.e., Relative Risk equal to or greater than 1.3), as per H.R. 162, or where a "statistically significant" excess of disease was associated with a particular exposure, as per S. 79. Table 1 considers occupations; Table 2 considers consumer products to which employees could be exposed during the course of work; and Table 3 considers other miscellaneous associations.

It should be noted that selected issues of only two journals were reviewed. Also to be noted are the number of associations reported with a risk which could trigger notification and the breadth and diversity of possible exposures which fall into the reportable condition category.

TABLE 1
OCCUPATIONS

With Relative Risk Equal to or Greater Than

1.3

OCCUPATION	HEALTH OUTCOME	R.R.	REFERENCE
Professional	Melanoma	2.9	Graham et al. AJE:1985;122;4
Managerial	"	1.8	"
Sales/clerical	"	1.7	"
Semi-skilled	"	1.7	"
Graduate School	"	3.2	"
Some college	"	1.9	"
High school/ trade school	"	1.6	"
Farming	"	1.9	"
Sedentary Jobs	Colon Cancer	1.3	Gerhardsson, et al. AJE;1986;123;5
Wood Worker (wood dust)	Selected Cancers	1.5	Siemiatycki, et al. AJE;1986;123;2
Syn. Fiber	Selected Cancers	1.8	"
Grain Handler (grain dust)	Selected Cancers	2.6	"
Paper Handler (paper dust)	Selected Cancers	2.0	"
Mechanical/ manual work	Child Leukemia (mother's occupation)	2.0	VanSteensel, et al. AJE;1985;121;2
Trade/transp.	" "	1.3	"
Domestic/ hotel/cater	" "	2.8	"
Education	" "	1.3	"
All Occupations	" "	1.3	"

OCCUPATIONS

With Relative Risk Equal to or Greater Than

1.3

OCCUPATION	HEALTH OUTCOME	R.R.	PREFERENCE
Domestic/ hotel/cater	(father's occupation)	1.5	Van Steensel, et al. AJE;1985;122;4
Medical/Soc.Serv.	" "	2.8	"
Lead Smelter	Mortality (Renal dis.)	1.9	Selevan, et al. AJE;1985;122;4
Lead Smelter	Mortality (Resp. dis.)	1.8	"
Lead Smelter	Mortality (TB)	1.3	"
Lead Smelter	Mortality (Kidney cancer)	2.0	"
Lead Smelter	Mortality (Injuries)	1.4	"
Agriculture	Mortality (under age 65 - lymphoma, myeloma)	1.5	Pearce, et al. AJE;1985;121;2
Forestry	Mortality (Hodgkins lymphoma)	1.3	"
Orchardist	Mortality (lymphoma, myeloma)	5.5	"
Poultry	Mortality (lymphoma, myeloma)	1.7	"
Professional/ technical	Mortality (lymphoma, myeloma)	1.3	"
Top SES	Mortality (lymphoma, myeloma)	1.4	"
NC Farmers	Mortality - all causes	1.6	Delzell & Gruff AJE;1985;121;3
Truck and auto mech.	Bladder cancer	1.3	Smith, et al. AJPH;1985;75;8
Copper Smelter (live near)	Mortality (Lung Cancer)	2.0	Pershagen & Goran AJE;1985;122;4

OCCUPATIONS

With Relative Risk Equal to or Greater Than

1.3

OCCUPATION	HEALTH OUTCOME	R.R.	PREFERENCE
Copper Smelter (work there)	Mortality (Lung Cancer)	3.0	Pershagen & Goran AJE;1985;122;4
Copper Miner	Mortality (Lung Cancer)	4.1	"

TABLE 2

PRODUCTS

With Relative Risk Equal to or Greater Than

1.3

PRODUCTS	HEALTH OUTCOME	R.R.	REFERENCES
Chocolate	Stomach cancer	1.8	Risch, et al. AJE:1985;122;6
Carbohydrates	" "	1.5	"
Nitrites	" "	2.6	"
Roast Lamb	Creutzfeldt-Jakob dis. (encephalopathy)	3.6	Davanipour, et al. AJE;1985;122;3
Pork Chops	"	6.1	"
Roast Pork	"	2.4	"
Ham (canned)	"	10.0	"
Smoked Pork	"	2.6	"
Scrapple	"	4.0	"
Liver	"	5.9	"
Coffee	Mortality	1.7	Kahn, et al. AJE;1984;119;5
Coffee	Mortality	1.4	Vandenbrouche, et al. AJE: 1986;123;2
Pigment Dyes	Childhood Leukemia (parent exposure)	1.8	VanSteensel, et al. AJE;1985;121;2
Chemicals	" "	2.4	"
Cleaning Prod.	" "	1.9	"
Aspirin (routine use)	Hairy Cell Leukemia	3.4	Oleske, et al. AJE;1985;121;5
Plastics	Alzheimer type dementia	3.0	Vena, et al. AJE;1985;122;3
Dry cleaning solutions	"	2.0	"
Textiles	"	4.0	"

PRODUCTS

With Relative Risk Equal to or Greater Than

1.3

PRODUCT	HEALTH OUTCOME	R.R.	REFERENCE
Anesthetic gases	Alzheimer type dementia	2.0	Vena, et al. AJE;1985;122;3
X-rays	"	7.0	"
Meat and poultry	Mortality (male)	1.7	Kahn, et al. AJE;1984;119;5
Eggs	Mortality (female)	1.3	"
Pepper	Mortality (both sexes)	1.3	"

TABLE 3

OTHER ASSOCIATIONS

With Relative Risk Equal to or Greater Than

1.3

RISK FACTOR	HEALTH OUTCOME	R.R.	REFERENCE
Birth Order (2nd born)	Childhood Leukemia	1.3	Shaw, et al. AJE;1984;119;5
Parental birth order	Childhood Leukemia (mother 1st born)	1.8	VanSteensel, et al. AJE;1985;121;2
Blue eyes	Melanoma	1.6	Graham, et al. AJE;1985;122;4
Marriage	Alzheimer type Dementia	2.3	Vena, et al. AJE;1985;122;3
Catholic Religion	"	2.2	"
Hay Fever	"	2.7	"

ATTACHMENT B

TESTIMONY OF

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ON

S. 79

THE HIGH RISK OCCUPATIONAL DISEASE

NOTIFICATION AND PREVENTION ACT OF 1987

BEFORE THE

LABOR SUBCOMMITTEE

OF THE

SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES

MARCH 19, 1987

Purpose

This report is intended to provide a basis for estimating the costs of implementing notification and subsequent follow-up, as described under S. 79.

Approach

For selected diseases, specific screening protocols were developed. The methodologies described below would be applied after a general epidemiological survey was conducted aimed at identifying diseases in excess among a particular population utilizing appropriate epidemiologic methods. The purpose is to identify the diseases to be targeted by the preventive intervention components of notification and subsequent follow-up.

With this phase, the notification and follow-up program has progressed from epidemiological studies identifying high risk groups to individual medical intervention. The disease specific protocols anticipate the general course of medical intervention and serve as a vehicle to identify medical monitoring components and cost estimates. It is recognized that the practical implementation of these schemes would rely on individual physician discretion; however, to provide estimates, generalized protocols were developed. In describing these models for notification and subsequent follow-up programs, five specific diseases were chosen as case studies.

Leukemias. Chosen because they have been associated with exposure to benzene.

Bladder cancers. Chosen because they are relatively common cancers which have been associated with occupational exposure; in addition, successful intervention is possible for this disease.

Colorectal cancers. Chosen because they are relatively common cancers associated with sedentary jobs.

Soft tissue sarcomas. Chosen because they are relatively rare non-specific cancers and have been studied for possible association with chemicals.

Peripheral neuropathy. Chosen because it is a non-malignant non-specific condition which has been associated with chemical exposure. It is illustrative of the type of general conditions likely to surface.

For each of these diseases, population screening and individual diagnosis protocols were developed for implementation among subgroups defined to be at high risk either through specific epidemiological work done under the S. 79 program or in the general medical literature.

This type of medical intervention as the follow-up to epidemiological evaluation is designed to produce a programmatic approach which is both medically sound and cost-efficient. The approach for each of the case study diseases is presented below as an intervention component flow chart. Common to each of the flow charts are the following:

- Administration to the defined population at risk of a disease specific targeted medical history.
- Cost-efficient application to the defined population at risk of available disease-specific screening tests.
- Physician intervention at the appropriate time for individuals.
- Subsequent periodic reevaluation of specific individuals in the high risk groups.

Each flow chart begins at the point where a high risk group has been identified, for example, through a case control study and notified. General and targeted medical history questionnaires are administered to individuals within this group. The questionnaire is a cost-efficient tool designed to obtain critical medical history and other health related information.

For soft tissue sarcoma and peripheral neuropathy, information from the questionnaire determines whether the individual is screened further medically or reevaluated at a later time. The appropriate time interval for reevaluating would be disease specific and based on medical efficacy. For colorectal and bladder cancers, the questionnaire is supplemented by a relatively inexpensive self-administered screening test. For leukemias, the screening test requires medical personnel;

therefore, its applicability as an adjunct to the questionnaire for large populations would have to be determined on a case-by-case basis.

Physician intervention is immediate if the medical history is suggestive of specific disease, but usually is dependent on the outcome of the specific screening tests. The differential diagnosis and treatment components are physician specific; however, sample protocols for these components were considered to establish a basis for cost estimates.

Each of the surveillance flow charts was then applied to a hypothetical high risk population of 10,000, with estimates of "positive screens" for each screening test used as the indicator of the number of individuals who would be eligible for the subsequent level of screening. (See Tables 1 and 2). Summaries of the numbers of each specific test and other medical intervention likely to be required for the hypothetical population were then compiled.

As the basis for estimating the costs of treatment of diagnosed cases, it was assumed that the defined high risk groups exhibited a relative risk of 5.0 with respect to the general U.S. population. Arbitrary choice of a high relative risk allowed for cost-estimation based on a worst-case scenario. For example, if the background incidence of a particular condition is known to be 30 per

100,000, the assumed rate in the high risk group would be 150 per 100,000 (5x30), and the number of expected cases in the hypothetical population of 10,000 would be 15. For the subsequent screening procedures, it was assumed that individuals who screened positive would have an increment in relative risk to 7.5; those who screened negative had a relative risk decrement to 2.5. Therefore, if this group was comprised of individuals who had previously screened positive, the assumed rate would be 225 (7.5x30) and if they had previously screened negative, the assumed rate would be 75 (2.5x30), etc.

The data for these theoretical applications are presented in hypothetical application flow charts.

TABLE 1

Formula for Estimating Percentage of Population With Symptoms Suggestive of Targeted Diseases

$$\% = \frac{\text{number of patients presenting with symptoms suggestive of specific disease}}{\text{total number of patients presenting}} \times K$$

WHERE:

$$K = \frac{\text{total number of patients presenting at short stay U.S. hospitals in 1983}}{\text{estimated 1983 U.S. population}}$$

$K = 38{,}783{,}000 / 220{,}000{,}000$

$K = .176$

NOTE: In high risk population, percentage is multiplied by a relative risk factor of 5 for hypothetical applications to populations of 10,000.

SOURCE: Vital and Health Statistics: Detailed Diagnosis and Surgical Procedures for Patients Discharged from Short Stay Hospitals, DHHS. National Health Survey, Series 13, Number 82, 1983.

TABLE 2

Percentages of Positive/abnormals on Specific Screening and Diagnostic Tests

Test	% positive/abnormal
Bone marrow	90
Bladder biopsy	50
Intestinal biopsy	70
FOBT	6
CBC/Differential	10
Urinalysis/cytology	12
Barium Contrast Enema	85

SOURCE: Maryland Medical Laboratories,
Baltimore, Maryland

Hypothetical Application - Leukemias

The following flowchart tracks the number of individuals in a notified population of 10,000 who would require specific tests under a follow-up program. Numbers appear in parentheses beside specific tests. A summary of these data appear in Table 3.

Hypothetical Application Flow Chart for Leukemias

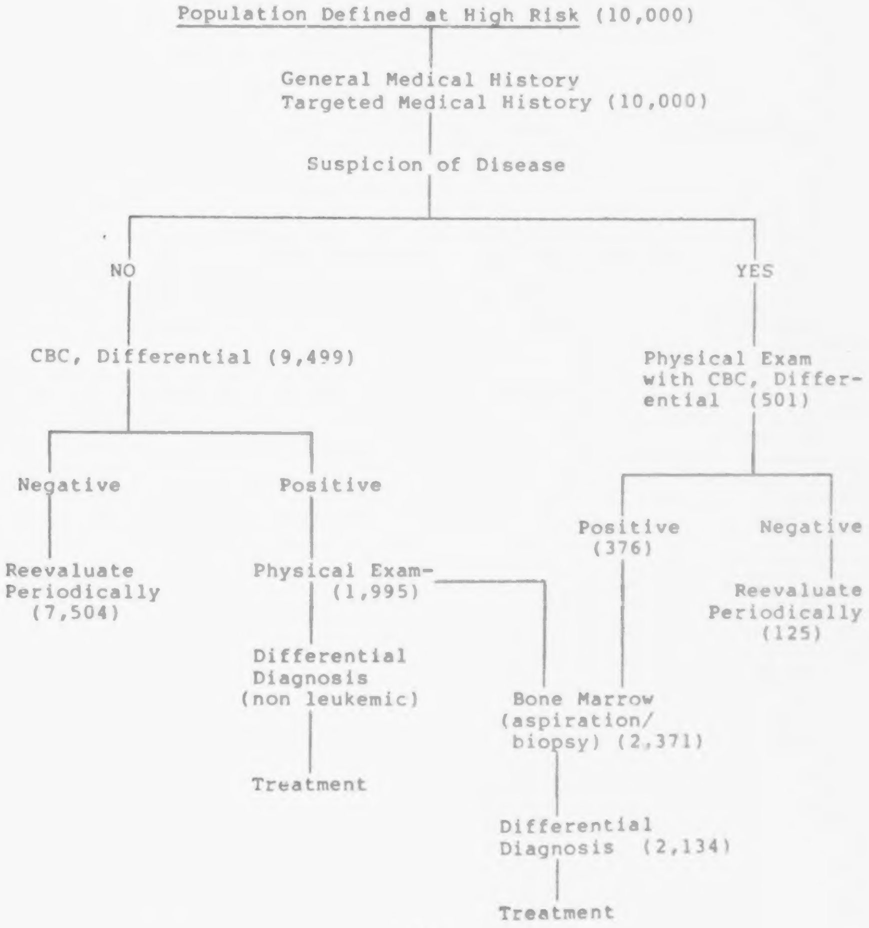

Population Defined at High Risk (10,000)
General Medical History
Targeted Medical History (10,000)
Suspicion of Disease
NO
YES
CBC, Differential (9,499)
Physical Exam with CBC, Differential (501)
Negative
Positive
Positive (376)
Negative
Reevaluate Periodically (7,504)
Physical Exam- (1,995)
Reevaluate Periodically (125)
Differential Diagnosis (non leukemic)
Bone Marrow (aspiration/biopsy) (2,371)
Treatment
Differential Diagnosis (2,134)
Treatment

TABLE 3

Summary of Hypothetical Application Flow Chart for Leukemias

(worst case assumed)

Test Administered	Number of Persons	Average Cost Per Worker	Total Cost
Medical History	10,000	$100	$1,000,000
CBC/differential	10,000	12	120,000
Physical Exams	2,496	100	249,600
Aspiration Biopsy	2,371	275	652,850
Differential Diagnosis Work-Up	2,134	275	586,830
			$2,080,305*

**Initial Reevaluation Pool 7,629

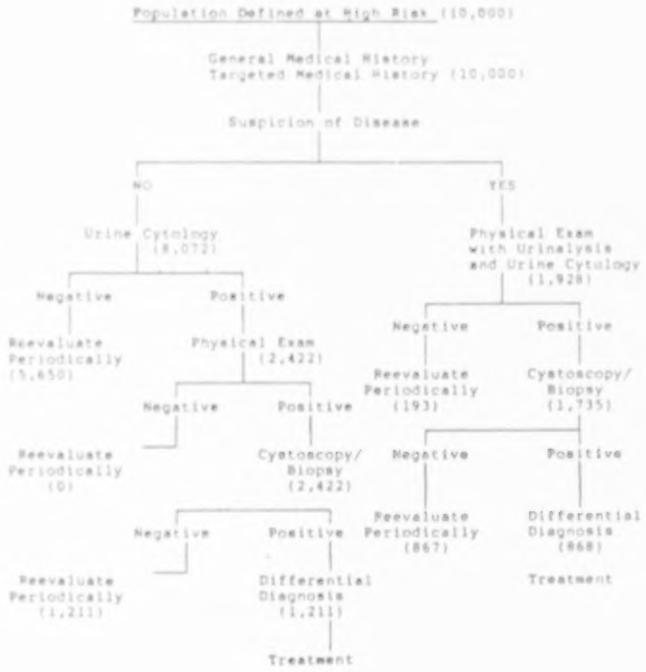
* For one pass through. Each year the cost will be approximately 24% less for monitoring; however, the costs for treatment, which are not included here, will increase.

** This group will be the target of the next phase of monitoring.

Hypothetical Application - Bladder Cancer

The following flow chart tracks the number of individuals in a notified population of 10,000 who would require specific tests under a follow-up program. Numbers appear in parentheses beside specific tests. A summary of these data appear in Table 4.

Hypothetical Application Flow Chart for Bladder Cancer


Population Defined at High Risk (10,000)
General Medical History
Targeted Medical History (10,000)
Suspicion of Disease
NO
YES
Urine Cytology (8,072)
Physical Exam with Urinalysis and Urine Cytology (1,928)
Negative
Positive
Reevaluate Periodically (5,650)
Physical Exam (2,422)
Negative
Positive
Reevaluate Periodically (193)
Cystoscopy/ Biopsy (1,735)
Negative
Positive
Reevaluate Periodically (0)
Cystoscopy/ Biopsy (2,422)
Negative
Positive
Reevaluate Periodically (867)
Differential Diagnosis (868)
Negative
Positive
Treatment
Reevaluate Periodically (1,211)
Differential Diagnosis (1,211)
Treatment

Note: No relative risk factor applied to results of cytoscopy biopsy since biopsies are probably being done on highest risk groups only.

TABLE 4

Summary of Hypothetical Application Flow Chart for Bladder Canders

(worst case assumed)

Test Administered	Number of Persons	Average Cost Per Worker	Total Cost
Medical History	10,000	$100	$1,000,000
Urinalysis and Urine Cytology	10,000	50	500,000
Physical Exams	4,350	100	435,000
Cytoscopy/Biopsy	4,157	400	1,662,000
Differential Diagnosis Work-Up	2,079	275	571,725
			$4,169,525*

**Initial Reevaluation Pool 7,921

* For one pass through. Each year the cost will be approximately 22% less for monitoring; however, the costs for treatment, which are not included here, will increase.

** This group will be the target of the next phase of monitoring.

Hypothetical Application - Colon Cancer

The following flow chart tracks the number of individuals in a notified population of 10,000 who would receive specific tests under a follow-up program. Numbers appear in parentheses beside specific tests. A summary of these data appear in Table 5.

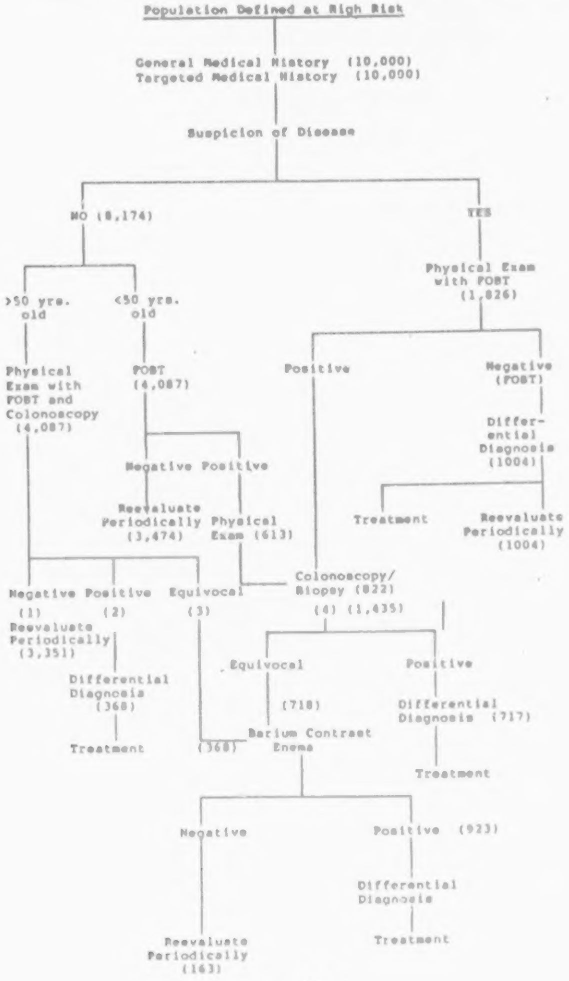

Population Defined at High Risk
General Medical History (10,000)
Targeted Medical History (10,000)
Suspicion of Disease
NO (8,174)
YES
>50 yrs. old
<50 yrs. old
Physical Exam with FOBT and Colonoscopy (4,087)
FOBT (4,087)
Negative
Positive
Reevaluate Periodically (3,474)
Physical Exam (613)
Physical Exam with FOBT (1,826)
Positive
Negative (FOBT)
Differential Diagnosis (1004)
Treatment
Reevaluate Periodically (1004)
Negative (1)
Positive (2)
Equivocal (3)
Reevaluate Periodically (3,351)
Differential Diagnosis (368)
Treatment
Colonoscopy/ Biopsy (822)
(4) (1,435)
Equivocal
(718)
Positive
Differential Diagnosis (717)
Treatment
(368)
Barium Contrast Enema
Negative
Positive (923)
Differential Diagnosis
Treatment
Reevaluate Periodically (163)

TABLE 5

Summary of Hypothetical Application Flow Chart for Colorectal Cancers (worst case assumed)

Test Administered	Number of Persons	Average Cost Per Worker	Total Cost
Medical History	10,000	$100	$1,000,000
FOBT	10,000	25	250,000
Physical Exams	6,526	100	652,600
Colonoscopy/Biopsy	1,435	500	717,000
Barium Contrast Enema	1,086	250	271,500
Differential diagnosis work-up	2,089	275	574,475
			$3,466,075*

** Initial Reevaluation Pool	7,992

* For one pass through. Each year the cost will be approximately 20% less for monitoring; however, the costs for treatment, which are not included here, will increase.

** This group will be the target of the next phase of monitoring.

Hypothetical Application - Soft Tissue Sarcoma

The following flow chart tracks the number of individuals in a notified population of 10,000 who would require specific tests under a follow-up program. A summary of these data appear in Table 6.

Hypothetical Application Flow Chart for Soft Tissue Sarcoma

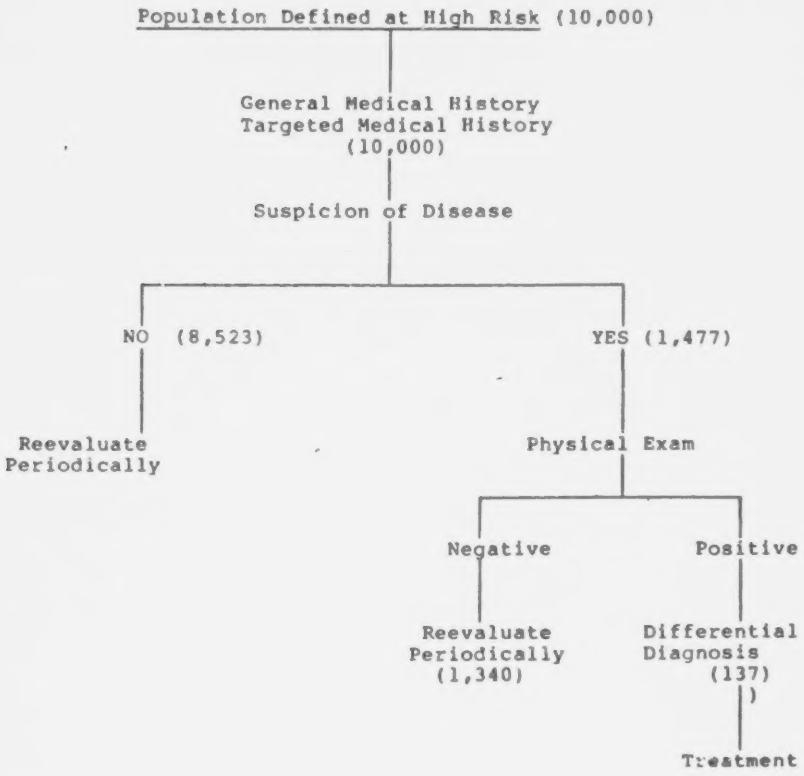

Population Defined at High Risk (10,000)
General Medical History
Targeted Medical History
(10,000)
Suspicion of Disease
NO (8,523)
YES (1,477)
Reevaluate
Periodically
Physical Exam
Negative
Positive
Reevaluate
Periodically
(1,340)
Differential
Diagnosis
(137)
Treatment

TABLE 6

Summary of Hypothetical Application Flow Chart for Soft Tissue Sarcoma (worst case assumed)

Test Administered	Number of Persons	Average Cost Per Worker	Total Cost
Medical History	10,000	$100	$1,000,000
Physical Exams	1,477	100	147,700
Differential Diagnosis Work-Up	137	275	37,375
			$1,185,375*

** Initial Reevaluation Pool 9,863

* For one pass through. Each year the cost will be approximately 1.5% less for monitoring; however, the costs for treatment, which are not included here, will increase.

** This group will be the target of the next phase of monitoring.

Hypothetical Application - Peripheral Neuropathy

The following flow chart tracks the number of individuals in a notified population of 10,000 who would require specific tests under a follow-up program. Numbers appear in parentheses beside specific tests. A summary of these data appear in Table 7.

Surveillance Flow Chart for Peripheral Neuropathy

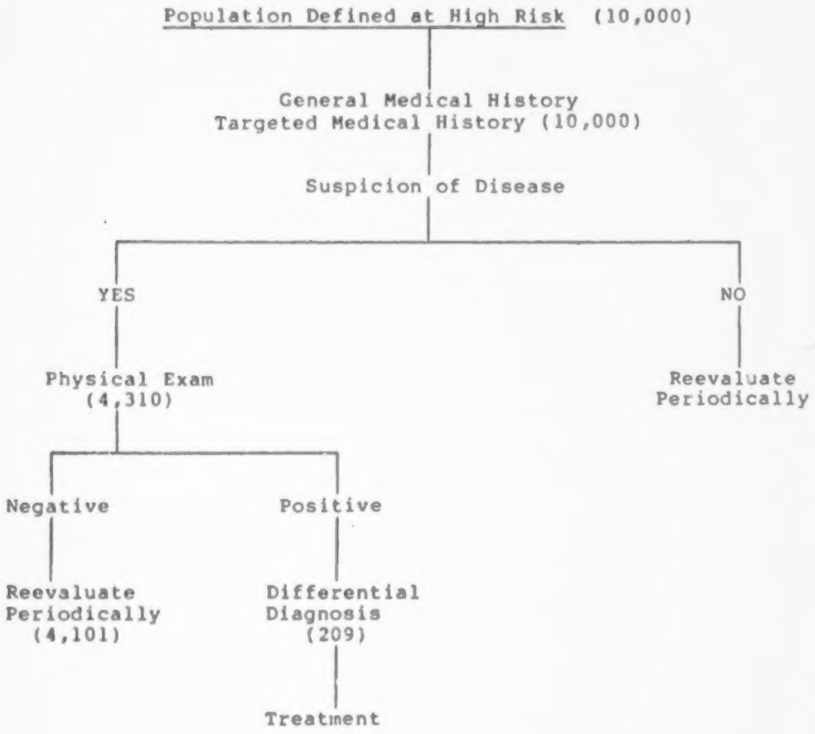

Population Defined at High Risk (10,000)
General Medical History
Targeted Medical History (10,000)
Suspicion of Disease
YES
NO
Physical Exam (4,310)
Reevaluate Periodically
Negative
Positive
Reevaluate Periodically (4,101)
Differential Diagnosis (209)
Treatment

TABLE 7

Summary of Hypothetical Application Flow Chart for Peripheral Neuropathy (worst case assumed)

Test Administered	Number of Persons	Average Cost Per Worker	Total Cost
Medical History	10,000	$100	$1,000,000
Physical Exams	4,310	100	431,000
Differential Diagnosis Work-Up	209	275	57,475
			$1,488,475*

**	Initial Reevaluation Pool	9,791

* For one pass through. Each year the cost will be approximately 2% less for monitoring; however, the costs for treatment, which are not included here, will increase.

** This group will be the target of the next phase of monitoring.

Table 8 contains estimated total costs for medical monitoring of 50,000 notified workers targeted for five selected diseases. It is conservatively assumed that the responsibility for follow-up will continue for ten years after notification. It is important to note that the costs of medical care associated with positive diagnoses are not included. In addition, indirect costs associated with probable litigation and workers' compensation claims derivative of the notification and follow-up program are not addressed.

TABLE 8

Follow-up Costs per 10,000 Workers

Year	Leukemia	Bladder	Colon	Soft Tissue Sarcoma	Peripheral Neuropathy
1	$2,080,305	$ 4,169,525	$ 3,466,075	$ 1,185,375	$ 1,488,475
2	1,581,032	2,252,230	2,772,860	1,167,594	1,458,706
3	1,201,584	2,536,739	2,218,288	1,150,081	1,429,531
4	913,204	1,978,565	1,774,630	1,132,829	1,400,941
5	694,035	1,543,352	1,419,704	1,115,837	1,372,922
6	527,467	1,203,815	1,135,764	1,099,099	1,345,464
7	400,875	938,975	908,617	1,082,613	1,318,554
8	304,665	732,401	726,887	1,066,374	1,292,183
9	231,545	571,273	581,511	1,050,378	1,266,340
10	175,974	445,593	465,209	1,034,622	1,241,013
Total	$8,110,686	$17,372,559	$15,469,545	$11,084,802	$13,614,129

ATTACHMENT C

TESTIMONY OF

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ON

S. 79
THE HIGH RISK OCCUPATIONAL DISEASE
NOTIFICATION AND PREVENTION ACT OF 1987

BEFORE THE
LABOR SUBCOMMITTEE
OF THE
SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES

MARCH 19, 1987

Table 1 contains total estimated costs for notification and follow-up of a total of 100,000 workers targeted for five selected diseases. A modest $5,000,000 per year is estimated to carry out the epidemiological work necessary to identify high risk groups. Medical costs associated with positive disease diagnoses are not included. Indirect costs of likely litigation and workers' compensation claims derivative of the notification and follow-up program are also not addressed. To meet the quota of 100,000 workers notified per year as provided in S. 79, the cost will approach $383,000,000.

TABLE 1

Total Estimated Costs for Notification and Follow-up under S. 79

Item	*Estimated Cost
**Administration and Notification (years 1 and 2)	$50,000,000
Workers Notified (year 1) (50,000)	
Epidemiological Studies to Identify High Risk Groups (50 studies @ $100,000)	$5,000,000
Medical Monitoring	$65,651,721
Workers Notified (year 2) (50,000)	
Epidemiological Studies to Identify High Risk Groups (50 studies @ $100,000)	$5,000,000
Medical Monitoring	$65,641,721
Cost for 100,000 workers	$191,303,442
Total Cost to Meet Quota Under S. 79	$382,606,884

* Medical care costs are not included.

** Level of funding provided for in S. 79, Section 14 ($25,000,000 per year).

Senator **Quayle**. Gentlemen, thank you very much.

With that, the Committee stands adjourned.

[Whereupon, at 12:15 p.m., the Subcommittee was adjourned.]

○

74-360 (304)